

Packets made from seaweed sturdy enough to contain liquids © Ooho

**302**

## BUILDING A SUSTAINABLE FUTURE FROM OUR OCEANS

TO ADDRESS MODERN-DAY SUSTAINABILITY  
CHALLENGES, THE EMBRC-ERIC WAS ESTABLISHED  
TO BRIDGE THE GAP BETWEEN MARINE BIOLOGICAL  
RESEARCH AND INNOVATION

## IN THIS ISSUE

**18**

**Paola Testori Coggi** speaks  
to Open Access Government  
about her work on defending investments  
in public health and the White Paper on  
food safety

**188**

**Jim Siegrist**, Associate Director at  
the U.S. Department of Energy details  
how the organisation is building for discovery,  
using the excellent example of their High Energy  
Physics program

**192**

**John Halligan TD**, Minister of  
State for Training, Skills, Innovation,  
Research and Development charts the  
research and innovation landscape in  
Ireland today

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**TO DO:**  
DEVELOPMENT OF CULTURAL AND  
CREATIVE INDUSTRIES IN PRACTICE



ANNA LINTON AND JONAS MICHANEK

## GREEN SHIFT

A HANDBOOK FOR ENVIRONMENTALLY  
FRIENDLY REGIONS IN EUROPE

EXAMPLES FROM REGIONS IN ÖRESUND, KATTEGAT AND SKAGERRAK



SVEIN TVEITDAL

## GREEN SHIFT

A HANDBOOK FOR ENVIRONMENTALLY  
FRIENDLY REGIONS IN EUROPE

This book is about the challenges and opportunities related to the green shift; that is to say, the necessary transition to the low-emission society the world needs in order to limit global warming to two degrees. The book provides a short overview, based on the most recent reports issued by the UN Panel on Climate Change, of the global problem posed by climate change.

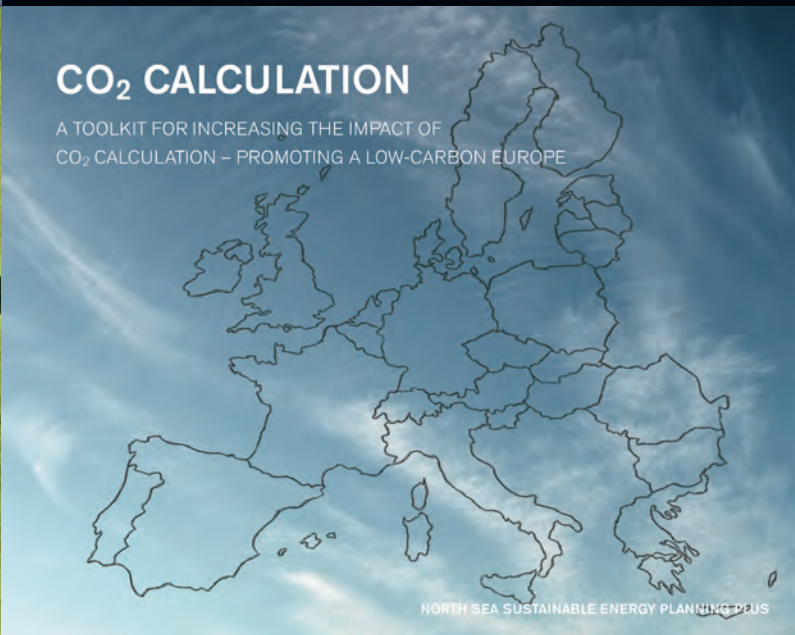
## TO DO

DEVELOPMENT OF CULTURAL AND  
CREATIVE INDUSTRIES IN PRACTICE

Welcome to a handbook that addresses you who work with regional development of cultural and creative industries! For example you, Eva Leemet at Creative Estonia or you, Michal Hladky at Kosice 2013, or you, Jone Zubiaga at Creativity Zentrum in Bilbao who showed great commitment and interest in this method handbook. We are writing for people like you who create fertile ground.

## CO<sub>2</sub> CALCULATION

A TOOLKIT FOR INCREASING THE IMPACT OF  
CO<sub>2</sub> CALCULATION – PROMOTING A LOW-CARBON EUROPE



NORTH SEA SUSTAINABLE ENERGY PLANNING PLUS

## CO<sub>2</sub> CALCULATION

A TOOLKIT FOR INCREASING  
THE IMPACT OF CO<sub>2</sub> CALCULATION

This toolkit is a product of an international cooperation project named North Sea Sustainable Energy Planning PLUS. With the aim of promoting a low-carbon Europe and increasing the impact of CO<sub>2</sub> calculation, partners from six countries have worked together to create this source of inspiration. The project was part funded by the European Union programme Interreg IV North Sea Region.

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Marian Krzaklewski



Jean-Pierre Haber

# FOREWORD

**Marian Krzaklewski**

**Member of the European Economic and Social Committee (EESC)**

European Economic and Social Committee

**Jean-Pierre Haber**

**Delegate of the Consultative Commission on Industrial Change (CCMI) at the EESC**

European Economic and Social Committee

Europe is an ageing continent. Thanks to the economic and social progress we have made, life expectancy has increased. However, ageing often comes with health issues and restricted mobility – a challenge not only for the elderly and their families but also for society.

Unfortunately, these issues connected with socio-demographic ageing in Europe have not yet had the attention they deserve. This also means that we are not yet aware of the major opportunities that decent care for our elderly can provide for economic development, employment and innovation in Europe.

## **Dignified ageing should be recognised as a fundamental human right**

It is our duty and obligation to promote equal access to high-quality care and services. We must find the right ethical, political, economic and social responses. Technology can help us cope with this challenge, provided that any ethical issues are sufficiently taken into account.

## **Anticipating the needs of elderly people**

As a first step, the needs of our older people need to be anticipated. To this end, we need appropriate statistical data. Demographic ageing should be measured in a dynamic and fine-tuned way, to include looking at variables, such as gender, healthy life expectancy and environmental epidemiology and dynamic indicators. A team of experts – demographers, sociologists, doctors – could set these variables up. We also suggest that national and regional ageing observatories should be established and that assessment tools should be put in place in Europe to observe and compare Member State policies and, thus, enable best practice to be replicated.



## **Creativity in the housing sector with high-tech devices**

Providing accommodation for the elderly is a complex and sensitive issue. Grouping elderly people together in one place does not offer any cognitive advantages. Scientific studies have already demonstrated the negative relationship between the mental and physical health of older people. In addition, taking over older people's care completely significantly increases their risk of becoming withdrawn and less resilient.

Since most elderly people want to remain in a familiar environment, appropriate housing is an important issue and, in our view, the choice can no longer be between live-in care and residential care homes.

Alternatives already exist, but we need more creativity and more investment in alternative housing, including the better use of digital technology innovation. The development of new homes should be based on the profiles and pathologies of older people, using high-tech equipment, yet we should also consider the social aspects by locating homes in developed parts of towns and in neighbourhoods that are not solely occupied by elderly people.

Telemedicine, sensors, a digital clinical card and digital medical records, as well as home automation technologies, would not only enhance older people's independence but would also make care more efficient and secure.

The European Union (EU) should take up the idea of age-friendly cities – as promoted by the World Health Organization (WHO) – and create a programme that supports pilot projects in different European cities or semi-rural areas. The aim of age-friendly cities is to optimise the health, integration and safety of older people.

Building and urban policies should also become more dynamic and flexible. Innovative housing schemes should be better promoted and supported by a specific funding programme under the European Structural Funds.

## **Harmonising education and facilitating access to training**

Caregivers play a crucial role in decent ageing, but this is not yet reflected in their social status and remuneration. Care and services for the elderly is also a sector

of the job industry, which offers a large number of employment opportunities.

Employers and employees of the European health and care services for the elderly sectors should steer the social dialogue, to ultimately lead to the establishment of a system of collective bargaining. Such a system for these sectors should cover both remuneration issues and vocational training, including obtaining digital skills.

The level of education of carers is inextricably linked to the wellbeing of elderly people. Issues such as nutrition, accidents at home, violence towards the elderly and towards professionals, the use of digital technology at home, end-of-life care, etc. should be incorporated into specific programmes that are funded by the European Structural Funds and the European Social Fund.

We advocate for a harmonised legal framework for personal services, including streamlining training for carers all over Europe. Access and training methods must be made simpler, for instance, by providing ICT tools that allow access to theory and information and creating communities and online platforms. This will facilitate the exchange of best practices.

## **Solid financial platform**

The EU and its Member States must encourage investment in improving the lives of older people, including in research and development. We propose a financial round table, bringing together the main stakeholders from both investors and care providers to discuss needs and possible financing options.

With this in mind, we encourage the Commission to conduct a study on the socio-economic outlook of care for our elderly. This study should also consider different forms of public and private funding, propose investment mechanisms based on public-private partnerships and put forward various recommendations at both supranational and Member State levels.

The needs of elderly people and the experiences of caregivers must come together to form the solutions of the future, supported by a sustainable financial system. ■





**Jonathan Miles**  
Editor

**Production Coordinator**  
Emma Faulkner-Dunn

**Designers**  
Andrew Bosworth  
Ben Green

**Sales**  
Debbie Cotterill  
John Hoinville  
Elena Adirkova

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DIGITAL POLITICS LIMITED

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Datum House  
Electra Way  
Crewe Business Park  
Crewe  
Cheshire CW1 6ZF

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# INTRODUCTION

It's an absolute delight to introduce the July 2019 edition of Open Access Government, which is now more comprehensive than ever.

Following the EHFG London event I attended on 2nd May, "Beyond the horizon – what will the world of research look like 10 years from now?" hosted by the European Health Forum Gastein, I interviewed Paola Testori Coggi, former Director General for Health and Consumers at the European Commission. Here, she speaks to Open Access Government about her work on defending investments in public health and the White Paper on food safety and the legislative action programme, as well as her work on the EU policy on consumer health after the food safety crisis.

As part of our fascinating research and innovation focus, I am very pleased to include editorial from Jim Siegrist, Associate Director for High Energy Physics at the Office of Science, U.S. Department of Energy, who details how the organisation is building for discovery, using the excellent example of their High Energy Physics program. In this section, it is an honour to include comment from John Halligan TD, Minister of State for Training, Skills, Innovation, Research and Development, who charts the research and innovation landscape in Ireland today.

This edition also features a number of high-profile pieces from the National Science Foundation in the United States. In one piece, Carol Bessel and Melissa Olson from the Division of Chemistry (CHE) reveal the organisation's goal of advancing basic chemical

research while also developing a globally competitive workforce. In another piece, I spoke to Juan Meza in the Directorate for Mathematical & Physical Sciences (MPS) about the launch of four new centres to bring mathematical perspectives to the biological search for the Rules of Life.

We also feature a brand new piece from Kevin Cunningham, Director General of the Government Digital Service in the United Kingdom, who explains how the organisation is transforming services and building digital capability across the public sector. We take this opportunity to wish him well in his upcoming new role in promoting government services around the world.

Very recently, I enjoyed a most interesting conversation with Andrea Jelinek, Chair of the European Data Protection Board about the consistent application of data protection rules throughout the European Union, including the use of personal data during election campaigns. Following the introduction of the General Data Protection Regulation (GDPR) just over one year ago, I feel that this is a very timely piece.

Feel free to get in touch if you have any suggestions for policy-themed content for future editions of Open Access Government, with many more in the pipeline for October 2019 and beyond.

**Jonathan Miles**  
Editor



@Jonathan\_AdjDig



# CONTENTS

OPEN ACCESS GOVERNMENT | JULY 2019



## HEALTH & SOCIAL CARE

**14 All for one and health for all: The EU scale to improve national healthcare systems.** José Inácio Faria MEP, Group of the European People's Party (Christian Democrats) explains the approach of taking advantage of the EU scale to improve national healthcare systems

**18 The European Commission: Defending investments in public health.** Paola Testori Coggi, Former Director General for Health and Consumers, European Commission speaks to Open Access Government about her work here on defending investments in public health and the White Paper on food safety and the legislative action programme, as well as her work on the EU policy on consumer health after the food safety crisis

**26 New challenges for public health in the 21st century.** Dineke Zeegers Paget, Executive Director of the European Public Health Association (EUPHA) provides a fascinating glimpse of the new challenges for public health in the 21st century

**32 Health: The priorities of the European Commission.** The priorities of Vytenis Andriukaitis, the current European Commissioner for Health & Food Safety are explained here, with the examples of antimicrobial resistance, big data and transparency to support science and innovation, amongst others

**40 Addressing gaps in systemic lupus erythematosus management.** Lupus is on the rise, yet awareness of the disease remains relatively low. However, efforts are underway to tackle existing gaps in managing the condition, as we discover here, as well as the European Commission's strong support for rare diseases more generally

**44 The development of precision medicine and biobanking initiatives in the Russian Federation.** In this insightful article, experts highlight recent developments in the field of precision medicine research and biobanking infrastructure in Russia, boosting national biomedical research programmes and facilitating integration into global research networks

**46 Health research and genomic data in Finland.** In this question and answer interview, Liisa Maria Voipio-Pulkki, Director General of Strategic Affairs and Chief Medical Officer at the Finnish Ministry of Social Affairs and Health, shares her thoughts on the health research landscape and genomic data in Finland

**52 A focus on rare disease: Paroxysmal nocturnal haemoglobinuria (PNH).** Maria Piggan, Chair of PNH Support tells us about the rare disease, paroxysmal nocturnal haemoglobinuria (PNH) and in this area, collaborations for change

## MENTAL HEALTH

**56 Universal Credit and mental health: "It was a confusion".** Carolyn Lochhead manages public affairs and communications at mental health charity SAMH (Scottish Association for Mental Health). In this article, she reveals the findings of a report that underlines the charity's report concerning Universal Credit and the impact it has on mental health

**62 What is the future of online mental health treatment?** Henry Jones spoke to Nishat Choudhury from Open Access Government about mental health platform Big White Wall (BWW), in light of the oncoming UK Government White Paper on Online Harms

## MEDICAL CANNABIS

**72 Cannabinoids for therapeutic purposes – where are we?** Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group shares a perspective on the present status and potential evolution when it comes to cannabinoids for therapeutic purposes

**82 Why cannabidiol (CBD) really is the next big thing.** From the stories appearing about cannabidiol (CBD) and its near miraculous effects, to the pharmaceutical companies rushing to catch up, it seems everyone is taking about cannabidiol

**91 We need to talk about access to medical cannabis.** Ramya Sriram, Digital Content Manager at Kolabtree, explains why many patients in the UK still cannot access medical cannabis and how scientific communication and further research can lead to change

**100 An overview of medicinal cannabis research.** Dr Mark Ware, Chief Medical Officer at Canopy Growth, provides an overview of the research that already exists around medicinal cannabis and explains why there is a need to educate clinicians further



## ASIA FOCUS

**106 Japan: Challenges around global data sharing for orphan diseases.** Makoto Suematsu, President of the Japan Agency for Medical Research and Development (AMED) details the challenges around global data sharing for orphan diseases

**108 A look at the Hong Kong Elderly Health Service.** With a growing elderly population – and with it, a growing number of carers – Hong Kong's Elderly Health Service has an increasingly important role in promoting both good physical and mental health, as this article reveals

## CANCER

**112 Preventing cancer: A whole-of-society, whole-of-government approach.** World Cancer Research Fund's Policy & Public Affairs Manager, Fiona Sing, outlines what governments and society should be doing to prevent cancer and other non-communicable diseases

## DIABETES

**116 The hunt for an alternative to century-old Type 1 diabetes treatment.** Dr Elizabeth Robertson, Director of Research at Diabetes UK details the hunt for an alternative to century-old Type 1 diabetes treatment – and looks at how British diabetes research is demanding something better

**122 Diet and Type 2 diabetes: Why a person should never be judged on what they eat.** The IDEAL group shares their thoughts on diet and Type 2 diabetes and explain why a person should never be judged on what they eat

**126 Diabetes focus: The role of nutraceuticals in preventing illness.** Pete Tate, CEO and Founder of MedTate, explains the role of nutraceuticals in preventing illness when it comes to diabetes in the UK

**130 How diabetes can affect the eyes.** With diabetes on the increase in the UK, Dr Louise Gow, Specialist Lead for Eye Health at The Royal National Institute of Blind People (RNIB) explains more about the condition and how it can affect the eyes

## STROKE

**134 The National Stroke Programme for England: How to achieve world-class stroke care.** Juliet Bouverie, Chief Executive of the Stroke Association, tells us how the NHS Long Term Plan and National Stroke Programme have the potential to transform stroke services across England in the next five years

## INFECTIOUS DISEASES

**138 The burden of viral hepatitis in the WHO Region of Africa.** Ahead of World Hepatitis Day on 28th July 2019, the WHO Regional Office for Africa detail the key issues when it comes to the burden of viral hepatitis in the WHO Region of Africa

## INFECTION CONTROL

**144 Infection prevention: Overcoming challenges in sepsis diagnosis.** Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group discusses the concerns with overcoming challenges in sepsis diagnosis

## CARDIOVASCULAR DISEASE

**148 Cardiovascular disease: Opportunities and challenges in the digital health era.** In this interview, Chair of the ESC Digital Health Committee, Professor Martin Cowie, details the opportunities and challenges in the digital health era when it comes to the field of cardiovascular disease

## RESPIRATORY DISEASES

**155 Supporting the addition of asthma medications to the exemption list in the UK.** Dr Fred A. Wagshul, Pulmonologist and Medical Director at the Lung Center of America, explains why he supports the addition of asthma medications to the exemption list in the UK

## NEURODEGENERATIVE DISEASES

**160 A devastating cancer: The priorities for brain tumour research.** Chief Executive of Brain Tumour Research, Sue Farrington Smith MBE, outlines the priorities for research into brain tumours and why it is imperative we overcome this uniquely devastating cancer

## MUSCULOSKELETAL CONDITIONS

**166 Impact and early intervention: Clinical research into osteoarthritis.** Versus Arthritis speaks to award-winning rheumatologist Dr Fiona Watt about clinical research into osteoarthritis

## HEARING RESEARCH

**174 Hearing loss and the link with dementia.** If we address hearing loss, can we really decrease our risk of developing dementia? Mark Atkinson, Chief Executive Action of Hearing Loss investigates

## MEDICAL TECHNOLOGY

**178 Wise healthcare spending can deliver better outcomes.** Barbara Harpham, Chair of the Medical Technology Group, wants to see healthcare spending, particularly on medical technology, linked to tangible outcomes for patients, the economy and society



## RESEARCH & INNOVATION

**182 Bringing mathematical perspectives to the biological search for the Rules of Life.** Editor of Open Access Government, Jonathan Miles, spoke to Juan Meza at the National Science Foundation about the launch of four new centres to bring mathematical perspectives to the biological search for the Rules of Life

**188 Physics: Building for discovery in the global context.** Jim Siegrist, Associate Director for High Energy Physics at the Office of Science, U.S. Department of Energy details how the organisation is building for discovery, using the excellent example of their High Energy Physics program

**192 Ireland: A world leader in research and innovation.** John Halligan TD, Minister of State for Training, Skills, Innovation, Research and Development charts the research and innovation landscape in Ireland today

**196 Looking ahead: Negotiating and managing the European Union budget.** Here, Editor of Open Access Government, Jonathan Miles, investigates the responsibilities of Guðther Oettinger, the European Commissioner for Budget & Human Resources in managing the European Union budget, including how it will benefit research

**202 Science and higher education for the future of Portugal.** Here, we speak to Manuel Heitor, Portuguese Minister of Science, about how science and higher education in Portugal are helping to turn the country into a knowledge hub for future generations, amongst other things

**214 UK priorities for science, research and innovation.** The UK is focusing on international partnerships and ground-breaking sector deals in order to remain a global leader in science. Here, we find out about the work of Chris Skidmore MP, the UK's Minister for Universities, Science, Research and Innovation and the Office for Life Sciences

**218 Boosting culture, heritage, science and innovation in the Netherlands.** The Government of the Netherlands has launched a major funding drive to support the arts, culture and heritage sectors in the Netherlands, as well as in science and innovation, headed up by Minister of Education, Culture and Science, Ingrid van Engelshoven

## CHEMISTRY

**222 Advancing basic chemical research while developing a globally competitive workforce.** Carol Bessel and Melissa Olson from National Science Foundation's Division of Chemistry (CHE) reveal the organisation's goal of advancing basic chemical research while also developing a globally competitive workforce

**230 Chemistry for the future of Europe.** Alex Schiphorst, Science Communication and Policy Officer discusses the vital role of chemistry when it comes to the future of Europe

**236 Cutting-edge life sciences and technologies: Assessing chemicals exposure toxicity.** Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group explains cutting-edge life sciences and technologies that assess exposure toxicity when it comes to chemicals, including novel tools to address human health and environment

## BIOLOGY

**242 Reading the warning signs: Research needed to address the crisis of maternal mortality.** Dr Diana W. Bianchi, Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the U.S. National Institutes of Health, details the critical need for research to address maternal mortality

**250 Exploring the emerging role of tumour necrosis factor receptor-associated factor 6.** Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group explores the emerging role of tumour necrosis factor receptor-associated factor 6 including the challenges and opportunities in this vein

**252 Ophthalmology: A focus on uveitis – the inflammation of the uveal tract.** Dr Gerry Morrow explains what you need to know about an aspect of ophthalmology called uveitis, defined as inflammation of the uveal tract, which comprises the iris, ciliary body and choroid

**253 Supporting vision research in the U.S. that encompasses visual impairment diseases.** Here, Open Access Government explore how the National Eye Institute in the U.S is supporting vision research that encompasses visual impairment diseases of people of all ages

## POLITICS RESEARCH

**256 Exiting the trade maelstrom in a progressive way.** Vassilis Ntousas, Senior International Relations Policy Advisor at the Foundation For European Progressive Studies shares his thoughts on exiting the trade maelstrom in a progressive way





## THE BUILT ENVIRONMENT

**258 Cities proving to be the real climate champions.** Anna Lisa Boni, Secretary General, EUROCITIES provides an absorbing insight into how cities in Europe are proving to be the real climate champions

**264 Places with purpose: Reinvigorating Britain's town and city centres.** Cllr Peter Box, Leader of Wakefield Council and Chair, Key Cities Group explains how Britain's town and city centres face significant challenges in redefining their purpose for local residents, visitors and businesses

## ENVIRONMENT

**270 Why championing recycling can help to combat climate change.** Ranjit Baxi, Bureau of International Recycling (BIR) President and Founding President of the Global Recycling Foundation, comments on the links between recycling and climate change, as well as the success of the celebrated Global Recycling Day 2019 on 18th March in cities around the world

**272 The Europe Commission's priorities for the environment.** Here, we focus on the European Commission's priorities for the environment, including water management and air pollution?

**276 Taxing and spending: How greening the fiscal and financial systems can help address environmental crises.** When it comes to taxing and spending, Dominic Hogg from Eunomia Research & Consulting shares his views on how greening the fiscal and financial systems can help address environmental crises

**280 Climate change: Science and scepticism.** Peter Jansen – Principal Lecturer and sustainable business expert, London School of Business and Finance, explains the science behind climate change and the barriers preventing people and businesses from acting

**284 An introduction to earthquakes in the U.S.** The U.S. Geological Survey (USGS) introduces what an earthquake is and what causes them to happen, plus the depth at which they occur

**288 The fight against climate change: We all foot the bill for a warmer Arctic.** Joseph Cook, Vice President of the UK Polar Network (UKPN) Committee argues that we all foot the bill for a warmer Arctic in the fight against climate change

**294 The priorities for domestic and international Arctic research in the United States.** The priorities for domestic and international Arctic research in the U.S., including the work of the United States Arctic Research Commission (USARC), are detailed here

## MARITIME AFFAIRS

**300 A new vision of plastic production and plastic use.** Antonello Pezzini, Member of the European Economic and Social Committee shares his new vision of plastic production and plastic use

**304 Can innovation and new technology tackle environmental issues in the marine environment?.** Tessa Harding, Director, Aquatic Ecology, at Thomson Environmental Consultants asks if innovation and new technology can tackle environmental issues in today's marine environment

**308 Conserving coastal and marine ecosystems and resources.** The National Oceanic and Atmospheric Administration (NOAA) have a mission to understand and predict changes in weather, climate, oceans and coasts, as this article reveals, with a special focus on their work to conserve and manage coastal and marine ecosystems and resources

**314 Biofouling: Aliens in the Baltic Sea.** Dominik Littfuss, HELCOM Communication Secretary explains the biofouling – the attachment of living organisms to the hull of ships – one of the main vectors of invasions of aquatic ecosystems from alien or non-indigenous species



## AGRICULTURE

**318 Systems approaches: Making pests run a gauntlet to safeguard crops and forests.** Greg Rosenthal of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service details the importance of the multiple safeguards in systems approaches – when it comes to making pests run a gauntlet to safeguard crops and forests

**322 The value of plant science in Europe today.** The European Plant Science Organisation (EPSO) reveals its thoughts on the value of plant science and the many improvements it can generate in areas such as sustainable agriculture, forestry and environmental conservation

**326 The popular potato crop and the major threat of blight (early and late).** Aarthi Janakiraman, Industry Manager, Chemicals and Advanced Materials at TechVision, Frost & Sullivan, shares his thoughts on the popular potato crop, as well as the potato blight (both early and late) which remains a major threat to production

**330 Studying and advancing the field of plant pathology.** The British Society for Plant Pathology's aims of studying and advancing the field of plant pathology are explored here, including the importance of advancing education in the field?



## ENERGY

**334 Building innovation ecosystems to support the energy transition.** Dr Christoph Frei, Secretary General of the World Energy Council shares his thoughts on building innovation ecosystems to support the energy transition

**340 Hydrogen helping the environment, reducing carbon emissions.** Morry Markowitz, President of the Fuel Cell and Hydrogen Energy Association details how policies have been implemented that increase the role of hydrogen in various applications – including transportation as one method reducing carbon emissions

**346 Bridging the gap to a decentralised energy future.** Aggreko's Managing Director of Northern Europe, Chris Rason, provides his thoughts on bridging the gap when it comes to a decentralised energy future in the UK

**350 Building Regulations: Why they're no longer fit for purpose.** Adrian Judd, Director of Steico, argues Building Regulations need to tighten up so that we build healthy buildings

**356 The future of the renewable energy market in Asia.** The future of the renewable energy market in Asia is explored here by VHR Global Recruitment, including a focus on Taiwan's ambition to phase out nuclear power by 2025

**360 Japan: A glimpse into environment and energy issues.** The work of the Ministry of the Environment and Ministry of Economy, Trade and Industry in the Government of Japan are examined here



## TRANSPORT

**364 Active safety: Paving the way for safe and efficient autonomous mobility.** David Paja, Senior Vice President and President, Advanced Safety & User Experience at Aptiv, provides his opinion on active safety and how this is paving the way for safe and efficient autonomous mobility



## INDUSTRY

**368 A focus on battery development in Europe.** EIT InnoEnergy is the industrial actor for the European Battery Alliance (EBA) and as such, they steer this activity. Here, Bo Normark, Thematic Leader Smartgrids & Storage, EIT InnoEnergy explains precisely why the EBA is the catalyst for battery development in Europe

**370 The priorities of the internal market, industry, entrepreneurship and SMEs in Europe.** The priorities of Elżbieta Bieńkowska, the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs are charted here, including her thoughts on social innovation





## LEGAL AFFAIRS

**376 The European Court of Justice and consumer protection.** Trevor Tayleur, Associate Professor and Head of Design and Assessment at The University of Law, explains the work of the European Court of Justice and their work around consumer protection



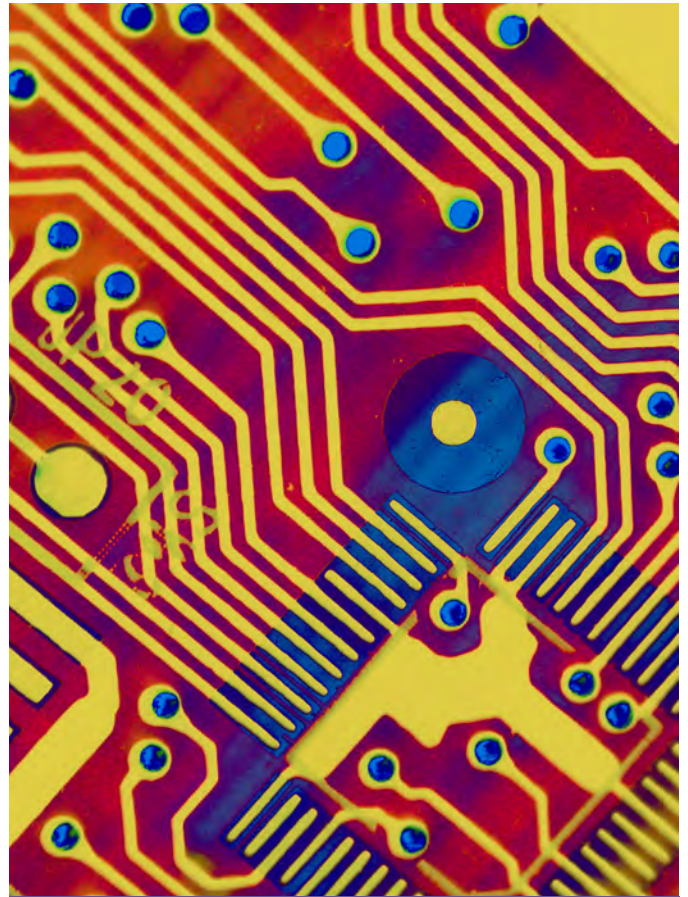
## GOVERNMENT

**382 Portugal in the limelight of companies looking to expand in the EU region.** Companies are continuing to expand into Portugal and the country is reaping the economic benefits of the added exposure, Bernardo Trindade, President of the Executive Committee of Portugal IN explores

**384 Consumer confidence in the safety of products.** Graham Russell, Chief Executive of the Office for Product Safety and Standards, explains why consumer confidence in the safety of products is at the core of what the organisation does

**386 Wider Public Sector Legal Services (RM3788).** Mark Jones, Commercial Agreements Manager – Legal Services at Crown Commercial Service discusses the Wider Public Sector Legal Services (RM3788)

**394 Smarter working: Improving employees' performance.** Dr Shahnaz Hamid, Programme Leader at InterActive Pro and Edology.com, tells us how smarter working improves employees' performance



## ICT

**398 How GDS is transforming services and building digital capability across the public sector.** Kevin Cunnington, Director General of the Government Digital Service (GDS) explains how the organisation is transforming services and building digital capability across the public sector in the UK

**412 Redefining success and motivation.** Offering flexi-time is not agile working. Individuals need to feel valued – and that demands a fundamentally different approach to employee empowerment and trust, explains Adam Kene, Managing Director at Kene Partners

**418 The consistent application of data protection rules throughout the EU.** Andrea Jelinek, Chair of the European Data Protection Board spoke to Open Access Government about the consistent application of data protection rules throughout the European Union, including the use of personal data during election campaigns

**422 Leading the “Digital Single Market” and fighting cybersecurity.** Andrus Ansip, Vice-President of the European Commission in charge of Digital Single Market aims to lead the “Digital Single Market”, as this article explores, plus his priorities for fighting cybersecurity

**428 Strengthening cybersecurity in the U.S.** Here, we take a look at the work of the Department of Homeland Security when it comes to strengthening cybersecurity in the U.S., including the Cybersecurity and Infrastructure Security Agency Cybersecurity Division

**436 In a perfect partnership: How councils can get the most out of a tech provider.** London Borough of Barking and Dagenham Council's Cassandra Phillip lists the key steps to creating a successful partnership with a technology provider



## BLOCKCHAIN INNOVATION

**440 Blockchain: A revolution in marketing.** In this article, Harnil Oza explains how Blockchain technology is improving the world of marketing via information tracking, influencing consumer expectation and embracing transparency

**444 Blockchain and retail: A potential industry revolution.** This article discusses the potential of blockchain and retail: Could the technology be responsible for a profit increase for the sector in 2018?

**448 Why are central banks leading blockchain experimentation?** Here, the World Economic Forum discusses how central banks are among the most cautious institutions in the world, yet the first to implement blockchain experimentation



## HR & TRAINING

**464 Apprenticeships: A high-quality route to skilled employment.** The Rt Hon Anne Milton MP, Minister of State for Apprenticeships and Skills at the Department for Education details why apprenticeships are a high-quality route to skilled employment

**468 Executive coaching: The hidden benefit.** Ross Thompson at Arden University reveals the hidden benefit of executive coaching – which is the potential to unlock talent and capability via the promotion of candour and personal opinion

## EDUCATION



## FINANCE

**454 Strengthening a proactive fiscal policy in China.** This article provides insight into the work of China's Minister of Finance Liu Kun, who is responsible for strengthening a proactive fiscal policy in one of the world's biggest and most powerful economies

**460 Enabling and promoting economic research in Switzerland.** The aims of the Society of Economics and Statistics in Switzerland are discussed here, which includes enabling and promoting economic research and encouraging the work of young economists

**472 Children and young people with speech, language and communication needs.** Taking a system-wide approach for children and young people with speech, language and communication needs in England is the way ahead, argues Chief Executive of the Royal College of Speech and Language Therapists (RCSLT), Kamini Gadhok MBE

**474 The use of artificial intelligence (AI) in education.** Dr Elaine Garcia, Senior Programme Leader at InterActive Pro and Edology.com, explores the use of artificial intelligence (AI) in education

**476 Achieving excellence in science, technology, engineering and mathematics education.** Here, we examine the mission of the National Science Foundation's Directorate of Education and Human Resources to achieve excellence in science, technology, engineering and mathematics education





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# All for one and health for all: The EU scale to improve national healthcare systems

José Inácio Faria MEP, Group of the European People's Party (Christian Democrats) explains the approach of taking advantage of the EU scale to improve national healthcare systems

Even if healthcare is a Member State prerogative under the subsidiarity principle, the future ahead will pose several threats that will benefit from a European approach, one that will focus on better outcomes in health and pave the way to health systems performance optimisation.

**“According to recent findings by the EU Expert Group on Health Systems Performance Assessment, 20% of current expenditure in modern health care systems can be categorised as either ineffective or wasteful. Handling these inefficiencies correctly can save part of the budget without unintended consequences on accessibility or on the quality of care.”**

Member States individually and also collectively – out of the European budget – have been financing innovation especially in areas where a low return on investment does not allow for private venture. Still, the sustainability of healthcare has been put at stake with the high price of new technologies. Politicians now see with some suspicion whether innovation actually translates into greater benefits, or if the incredible amounts of money are not proportional to the little added value that these products, sometimes, actually bring. Centralising the clinical part of HTA in Europe has the potential to introduce more fairness in accessibility to true innovation for European citizens. Unfortunately, this will not translate immediately into higher affordability.

Our cheap old medicines in the market can be found to have new uses – repurposed medicines. Many candidates for repurposing are widely used low-cost generics. For example, the Repurposing Drugs in Oncology project identified more than 230 licensed non-cancer drugs with data supporting anti-cancer activity, of which over 75% are off-patent. As the drugs are already in routine clinical use, early phase clinical trials can be

bypassed, saving time and money. The same happens with combination therapies that use cocktails of inexpensive drugs with their synergic effect being greater than the sum of their parts. However, research in these areas is harder as the funding pathways are meagre because of the low-appealing financial return.

With the passing years, as medicines for cancer become less expensive, they become scarce in the market for more reasons than one. While stakeholders are entertained in the blame-game, passing on the responsibility for these shortages, none of them actually looks into his partaking in solving the problem.

The shortages of inexpensive essential medicines are a growing public health emergency that requires concerted and collaborative action at European Union (EU) level. While there is a clear impact of shortages on patient outcomes, the causes of shortages are complex and multifactorial – such as manufacturing planning, parallel import/export and poor reporting mechanisms – and cannot be solved by any Member State alone. Many European countries across the range of the EU are facing shortages of essential medicines and this pressing issue is currently threatening patient safety across Europe and severely limiting the ability of physicians to provide effective treatment regimens.

The impact of shortages, even for inexpensive essential medicines, has a significant impact on patient care. The lack of these crucial medicines can lead to failure to treat, delayed treatment and the use of less desirable, often expensive, alternative products. This is of particular concern in the field of oncology where, in many cases, there are no alternatives. Thus, shortages negatively affect both the health of European citizens and the sustainability of European healthcare systems through increased costs. For children diagnosed with





for medicines shortages, lists of essential medicines and legislation for early notification of supply disruptions. We also need to consider the financial incentives in place to address the economic causes of shortages and make essential shares of medicines remain on the markets where they are intended and manufactured for. Intervening on the pricing mechanisms can be an alternative, not necessarily imposing prices at the national level but establishing minimum indexed prices for exports in the EU.

National health systems face several other challenges and are not immune to the European single market. While this can be one of the reasons for shortages, as the low prices in some countries make it appealing for over-exploitation, it is also true for health professionals who will also be scarce in the future, according to the social sciences projections. Other challenges rise in the area of prevention and early detection as this has been deemed the smartest way to invest in health systems, even if outcomes are only measurable much after each government's mandate. I believe that cross-party longitudinal agreements for healthcare are the way forward in order to save avoidable health interventions and to curb higher costs of advanced stage treatment.

According to recent findings by the EU Expert Group on Health Systems Performance Assessment, 20% of current expenditure in modern health care systems can be categorised as either ineffective or wasteful. Handling these inefficiencies correctly can save part of the budget without unintended consequences on accessibility or on the quality of care.

The burden of disease is too high for negligent approaches. Health systems need more tools to work and the European scale and its solidarity model, which stands exemplary as a beacon for the rest of the world, can be a solution to many of the challenges at hand. ■

### **José Inácio Faria MEP**

Group of the European People's Party (Christian Democrats)

Tel: +32 2 28 45454

[joseinacio.faria@europarl.europa.eu](mailto:joseinacio.faria@europarl.europa.eu)

[www.europarl.europa.eu/meps/en/125101/JOSE+INACIO\\_FARIA/home](http://www.europarl.europa.eu/meps/en/125101/JOSE+INACIO_FARIA/home)

[www.twitter.com/JoseFariaMEP](https://www.twitter.com/JoseFariaMEP)

cancer, the situation can be particularly devastating as the medicines affected by shortages are curative and with few proven effective alternatives.

In addition, at the operational level, health professionals such as hospital pharmacists incur on major time losses in trying to find alternative treatments for patients, which, in turn, leads to increased costs for healthcare systems and higher costs of alternative treatments for payers. What is more, shortages have a direct economic impact on patients where the substitution with higher-cost medicines may fuel individual out-of-pocket payments.

It is my sincere belief that a European solution is required to tackle the problem as no one measure will suffice. Recommendations of the European Society for Medical Oncology endorsed by other stakeholders, health professionals and patient associations as well as several civil society organisations, have made the path quite clear. At the start of all measures, we need a clear definition of what constitutes a “medicine shortage” and this needs to be consistent throughout Member states. There is also a need for national strategic plans

# ENABLING WORKING CARERS

**Caroline Day from Wellbeing Dynamics discusses her thoughts on enabling working carers to look after a loved one**

1 in 8 people (6.5 million) are affected, Panorama is on the case and the situation is dire. I'm talking about being a carer for a loved one! Many of these carers need or want to work – and that gives employers a complex problem. How to support them in a way that also protects the business.

The trouble is that the word carer is used generically – but there are very different sorts of care. For example, I looked after my father until he was 94 and he was totally obliging and grateful at all times for every bit of help he received. A delight to look after, the only problem was organising everything so that his schedule worked with mine. But recently, I spoke with a carer who'd had to give up work because her mother has vascular dementia with challenging behaviour; she can be abusive for hours at a time. Very different situation. Very different pressures.

But, there's a huge swathe of employees whose parent's need a bit of help to stay independent. Their parents are starting to be infirm and just beginning to need help with things like shopping, lawn mowing, DIY etc. It's manageable and work is hardly affected.

Over time, they need a bit more help; perhaps now they need a visit every day to give them their supper. That involves extra shopping and cooking and getting there on time (parent gets anxious) which can mean missing important meetings at work that run over. By now, the employee is becoming exhausted, working all day and caring in the evening. And if they also have children there an additional concern about the family feeling neglected!

The difficulty arises when they become conflicted by the process. Effectively, they're trying to do a good job in three different environments. They really are the ham in the Sandwich of Life!

This can go on for years and sometimes people have no choice but to give up work. But these are valuable members of staff that are difficult to replace. It would be so much easier if they could be helped to fulfil all roles to their satisfaction – and actually, it's relatively simple.

I've spent the last 30 years helping people cope with difficult situations at work; from dealing with abuse at work to issues, such as bullying. These are the same skills that are needed to cope with the caring issue.

## **Resourcefulness**

I define this skill as the ability to know what to do and the bravery to carry it through. In a difficult situation, being able to draw on inner resources provides enormous opportunity to try something out and if it doesn't quite work the first time, do it differently. This is useful for work too.

## **Inner strength and resilience**

Some people have the ability to do five things and thrive, other people do one thing and fall over. Resilience is sometimes referred to as the level of bounce-back-ability. The strength to go through a challenge here and then go on to another challenge there with no cross-fertilisation of thoughts between the two is an immeasurable skill.





## Inner conflict

The person wants to be successful at work but feels torn with concern for their parent. This depletes energy and can leave them floundering. But actually, it's no longer the job or the caring that's the problem; it's the internal conflict of feeling they need to be in two places at the same time. Resolving this conflict restores their energy and gives them the freedom to manage better.

## Personal Wellbeing

A pre-requisite of being a useful carer is that the person looks after their own wellbeing. It's so important to keep the batteries charged. Giving yourself permission to look after yourself and putting the steps in place that need to be there, is a vital piece of the puzzle.

## What can you expect?

You can expect staff to be no longer conflicted by working and caring, instead managing both environments with clarity and authority. Retaining their identity as a working professional allows them to make better choices that respect themselves and their employer. Continually recharging their batteries allows them to deliver on all fronts.

But more than that, it gives employers a highly motivated workforce who appreciates the opportunity to both work and care for their loved ones.

**Information on the workshop Enabling Working Careers is available on our website:**

**[www.wellbeingdynamics.com](http://www.wellbeingdynamics.com)**



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# The European Commission: Defending investments in public health

Paola Testori Coggi, Former Director General for Health and Consumers, European Commission speaks to Open Access Government about her work here on defending investments in public health and the White Paper on food safety and the legislative action programme, as well as her work on the EU policy on consumer health after the food safety crisis

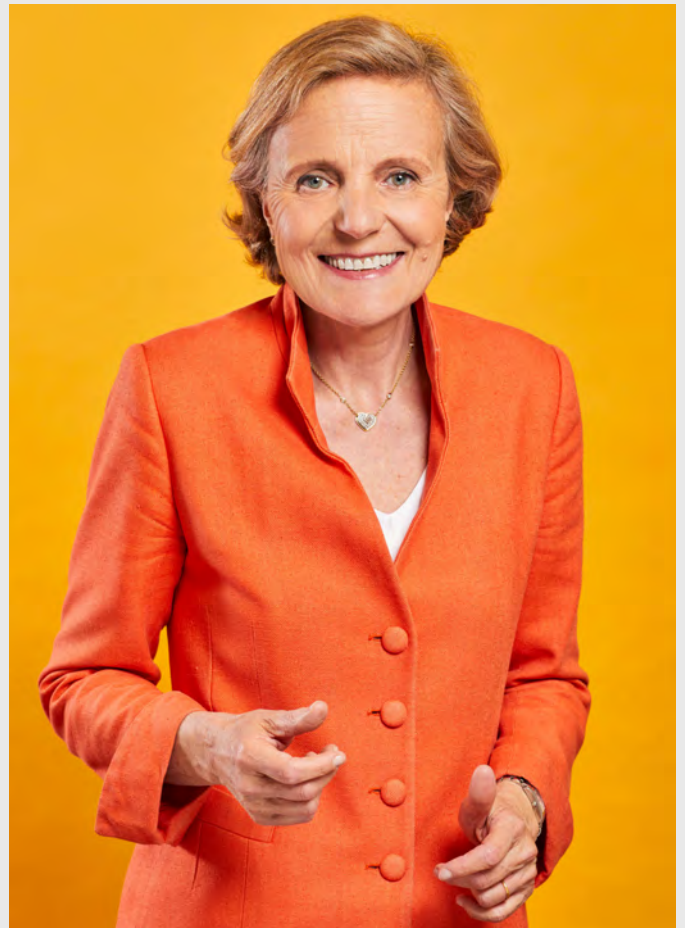
In this interview, Paola Testori Coggi, Former Director General for Health and Consumers, European Commission speaks to Open Access Government about her work here on defending investments in public health. As Director for the Food Chain Safety, we find out what work she carried out in the White Paper on food safety and the legislative action programme, as well as the management of emergencies.

In addition, Paola details the important work she did as Advisor for Consumer Health to Commissioner Emma Bonino, on the definition of the new European Union (EU) policy on consumer health after the food safety crisis. We also find out about what she is doing now as Chair of the Valletta Technical Committee on cooperation for better access to medicines and the priorities in this area.

If all that wasn't enough, Paola also highlights her current cooperation with the International Trade Center of the United Nations as Special Advisor on sanitary and phytosanitary matters – plus her views on the priorities should be for the next European Commissioner when it comes to supporting the policy areas of food safety and public health.

## **Tell us about your time as Director General for Health and Consumers of the European Commission**

I took office as Director General for Health and Consumers in 2010 when the financial and economic crisis was affecting severely public finances and public health budgets were kept under constant review in order to reduce expenditure and to achieve more efficiency. I defended strongly all investments in public



*Paola Testori Coggi, Former Director General for Health and Consumers, European Commission*

health – promoting the concept that better health is wealth and, therefore, health expenditure is not a cost but an investment.

To this aim, I succeeded in getting the Communication, Investing in health adopted by the Commission: this

Communication underlines that the investment in health systems, other than creating value for the health of each individual, contributes to social cohesion and helps reducing poverty and social exclusion. Secondly, sustainable investments and cost-effective spending bring savings and secure better health outcomes. Thirdly, health can boost economic growth by enabling people to work and remain healthier longer.

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**“I took office as Director General for Health and Consumers in 2010 when the financial and economic crisis was affecting severely public finances and public health budgets were kept under constant review in order to reduce expenditure and to achieve more efficiency. I defended strongly all investments in public health - promoting the concept that better health is wealth and, therefore, health expenditure is not a cost but an investment.”**

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I contributed to the adoption and implementation of the Directive on Patients' rights in cross-border health-care. This directive not only helps patients to exercise their rights for health treatments in any EU country but also creates the foundations for greater cooperation and integration in some areas of the national healthcare systems, such as the European reference networks on rare diseases and e-health.

**As Director for the Food Chain Safety, what work did you carry out on the White Paper on food safety and the legislative action programme, as well as the management of emergencies? What did this involve?**

The White paper on food safety was necessary because, after the crisis of the Mad Cow Disease in the late Nineties, it became clear that the EU legislation was not sufficient to guarantee the safety of the food chain. In the White Paper, we developed a radical new approach, including an independent agency for scientific advice, a reinforced body of EU inspectors and a completely new set of legislation covering the entire food chain from “farm to table”, emergency mechanisms in response to health emergencies throughout the food chain.

In the space of a few years, it was possible to adopt many regulations and measures because all EU Insti-

tutions and the Member States realised that the Union had to provide a rapid and effective response to regain citizens' trust and consumer confidence. The General Food Law, the pillar of the new policy adopted in 2002, is the most far-reaching piece of EU legislation in the area of public health and consumer protection: it established the European Food Safety Authority, it laid down general principles, requirements and procedures covering all stages of food and feed production and distribution and it created the Rapid Alert System for food and feed.

**As Advisor for Consumer Health to Commissioner Emma Bonino, what work did you do on the definition of the new EU policy on consumer health after the food safety crisis?**

I started to work with Commissioner Emma Bonino when the College, in response to the Enquiry Committee set up by the European Parliament in February 2007, decided to give the responsibility of developing the new policy on Consumer Health to Commissioner Bonino, which at the time was the most popular Commissioner thanks to her action in the humanitarian field. In a few months, with the Commissioner and a small group of very dedicated and competent colleagues, we prepared a complete re-organisation of the Commission services and identified a series of measures for better protection of consumer health and a higher level of food safety.

**What work are you doing now as Chair of the Valletta Technical Committee on cooperation for better access to medicines and what are the priorities for this?**

The objective of the Valletta Declaration, which has been signed by ten Member States, is to collaborate in order to improve patients' access to new and innovative medicines and to support the sustainability of the national health systems. I direct the discussions of the members for the identification and prioritisation of areas for cooperation and for the actions on assessments and pricing.

In this area, there are European, national and regional competences and we must take into account science, pharmaco-economy, sustainability, equity and innovation. So, as Chair of the Valletta Committee and previ-

*Continued on page 21 →*





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← Continued from page 19

ously as President of the Italian Committee for pricing and reimbursement of medicines, my thrust and my course of action is to find a common ground amongst all these aspects and the interests of the stakeholders, in order to guarantee access to medicines for all patients, while aiming at the sustainability of pharmaceutical expenditure and the promotion of research and innovation.

## **Tell us about your cooperation with the International Trade Center of the United Nations as Special Advisor on sanitary and phytosanitary matters**

I have been working with the International Trade Center in the area of technical assistance to developing countries in order to help them to comply with the international sanitary and phytosanitary measures. In particular, I have contributed to the development of a new scheme called Systematic and Emergency Support Mechanism for Safer Food, which has been financed by Regional Trade Related Assistance of the DEVCO programme. The specific objective of this mechanism is to increase food safety and competitiveness of agro-food products in certain developing countries through access to knowledge and compliance with sanitary and phytosanitary market access requirements.

## **What do you think the priorities should be for the next European Commissioner when it comes to supporting food safety and public health?**

One of the priorities in the area of public health, which should be pursued by the new Commission is the area of the performance of the health systems: we know that all national systems need to be reformed in order to face the challenge of sustainability and ageing of the population. This reform implies stronger governance, more efficient primary care, better-integrated care, new health workforce skill-mixes and introduction of innovative e-health solutions and innovative therapies. Cooperation and consultation at EU level, as well as EU financing mechanisms, can be of great help.

In the area of food safety, the priority of the next Commission should be to defend the European model of production, which has the best level of safety, sustain-

ability, quality and ethicality and to promote it in the world. This implies that our agricultural and food production should continue to be able to meet the high costs imposed by our stringent safety, environmental and social standards.

## **Is there anything you would like to add?**

I have always been working in the public sector -Italian regional administration, European Commission and lastly in the Italian Health Ministry- in policy areas of great social and economic impact, such as public health, food safety, consumer protection and the environment. It has been a great privilege for me to work in the areas of public service, for the res publica, with the objective of creating an efficient public administration at the service of the citizens and defending the well-being and the safety of consumers and patients, while taking into account also the interests of other stakeholders. ■

*This interview was organised following the EHFG London event "Beyond the horizon – what will the world of research look like 10 years from now?" held in conjunction with REL X and hosted by the Wellcome Trust. The event was hosted by the European Health Forum Gastein (<https://www.ehfg.org/>) in the lead up to their forthcoming event, EHFG 2019: A healthy dose of disruption? Transformative change for health and societal well-being in early October 2019, at Bad Hofgastein in Austria. Paola Coggi is also a member of the EHFG's advisory committee.*

**Paola Testori Coggi**  
**Former Director General for Health and Consumers,**  
**European Commission**

European Health Forum Gastein  
[info@ehfg.org](mailto:info@ehfg.org)  
[www.ehfg.org](http://www.ehfg.org)  
[www.twitter.com/gasteinform](https://www.twitter.com/gasteinform)

# Pharmacy education set to thrive at Swansea University

Swansea University is taking action to build on the increasingly important role of the pharmacist in healthcare by developing its new pharmacy degree

**W**ith the recent news that Welsh Government is almost doubling pharmacy training places in Wales with a £5 million boost – the new MPharm programme at Swansea University Medical School is perfectly timed.

A new Welsh Government campaign promotes Wales as a ‘top choice’ location for pharmacists to Train, Work and Live.

Swansea University Medical School has already started investing in its commitment to deliver first-class pharmacy education and training with the development of its new MPharm curriculum, recruitment of top pharmacy academics and establishing a strong pharmacy research team.

Professor Andrew Morris, the new Head of Pharmacy at Swansea University Medical School, has welcomed the Welsh Government investment and says it is an exciting time to train and work as a pharmacist in Wales.

Professor Morris says: ***“Pharmacy students who choose to come to Wales can benefit from a well-integrated healthcare system – the way the NHS is set up in Wales means it is far easier to share both knowledge and innovation across a wide range of settings – this then enables us to give patients the best care possible.”***

Professor Morris joins Swansea University Medical School – which is ranked 3rd in the UK for Medicine by the Times and Sunday Times Good University Guide 2019 – from the University of Nottingham, Malaysia Campus, where he was Dean of the Faculty of Science.

## Exciting times for pharmacy

Professor Morris says: ***“We are very excited to be launching our new MPharm degree here at Swansea in 2021 and have already recruited leading academics who will help us shape and deliver the course.”***

***“Dr Amira Guirguis, a pharmacist and senior lecturer, joins us from the University of Hertfordshire as MPharm Programme Director. Dr Adam Turner, joins us from the Royal Pharmaceutical Society in Wales as Senior Lecturer in Pharmacy Practice.”***

***“Adam brings some fascinating experience from the previous professional roles with the Royal Pharmaceutical Society in Wales and his various academic appointments both in England and internationally.”***

***“Adam’s recent practice experience in a variety of settings across Wales, including GP practice and urgent care, will mean that he has excellent insight into the real-life issues affecting health-care needs of patients and the public.”***

***“His wealth of pharmacy experience will be key as we develop a new MPharm curriculum to prepare future pharmacists for their expanding roles within the NHS.”***

## Leading research on drug misuse

But it is not just the vocational side of pharmacy that students at Swansea will benefit from, Dr Amira Guirguis brings a wealth of research expertise with her focusing on the in-field detection of emerging psychoactive substances.

Notable application of her work was a collaboration with Addaction, where Amira led on setting up the first government-approved Drug-Checking Service in the UK within a substance misuse setting. Her research interests also include Pharmacy Education and Public Health.

Professor Morris adds: ***“Her research focuses on drug misuse and particularly new psychoactive substances. This ground-breaking work has garnered significant media attention including TV appearances as far away as Australia.”***

***“Our pharmacy students at Swansea University Medical School will benefit from this novel research by understanding the roles of pharmacists in***





*identifying and classifying an unknown NPS particularly those associated with high-risk use.*

*"And our students will also be involved in practical laboratories and research projects related to this novel area of research thanks to the wealth of expertise Amira brings to the School.*

*"This is a very exciting time for Pharmacy education and training in Wales."*

Professor Keith Lloyd, Head of Swansea University Medical School, adds: **"With more and more pharmacists now needed to meet the increasing demand from patients, our new MPharm degree will help deliver first class**

*pharmaceutical care for people in Wales.*

*"We welcome this additional funding commitment from Welsh Government, and are working hard to ensure our new pharmacy degree is developed to meet the needs of the changing face of pharmacy."*

To find out more about Swansea University Medical School visit:  
[www.swansea.ac.uk/medicine](http://www.swansea.ac.uk/medicine)



**Professor Andrew Morris**  
**Head of Pharmacy**  
Swansea University Medical School  
Tel +44(0)179 260 6106  
[a.p.morris@swansea.ac.uk](mailto:a.p.morris@swansea.ac.uk)  
[www.swansea.ac.uk/medicine](http://www.swansea.ac.uk/medicine)  
[www.twitter.com/SwanseaMedicine](https://www.twitter.com/SwanseaMedicine)

# Welsh project aims to offer treatment as ovarian cancer cases continue to rise

A new £2.6 million project led by Swansea University Medical School aims to dramatically improve the diagnosis and treatment of ovarian cancer

The Cluster for Epigenomic and Antibody Drug Conjugate (ADC) Therapeutics (CEAT) project, which has been awarded £1.2 million in funding from WEFO, aims to utilise novel epigenetic drugs to manipulate chemical compounds creating a new route for the treatment of ovarian cancer – one of the deadliest forms of cancer for women – as incidences of the disease, particularly in younger women, continue to rise.

Cancer Research UK statistics show ovarian cancer is the sixth most common cancer affecting females in the UK, with around 7,300 new cases in 2015.

Advanced ovarian cancer has a five-year survival rate of only 5%. And the incidence of ovarian cancer in younger women continues to increase with a projected rate increase of 15% in the UK between 2014 and 2035 if no suitable interventions are developed and introduced into the NHS.

Dr Lewis Francis from Swansea University Medical School is one of the Principal Investigators from CEAT. Dr Francis also runs the School's successful MSc in Nanomedicine.

He says: ***"Epigenetics involves chemical changes to the DNA and associated proteins that can lead to genes being turned on or off. In some cases this can go wrong and lead to disease. Through the CEAT project, Swansea***



***University will work closely with CEAT partners to develop drugs that can control epigenetic signals; these epigenetic drugs can be targeted specifically towards ovarian cancer cells where epigenetic changes have occurred."***

Antibody Drug Conjugates (ADCs) are a powerful new class of therapeutics in medical oncology, where antibodies that target specific cancers are coupled with cytotoxic agents. CEAT, through extensive planning between

all project partners, has been developed as a systematic programme to advance a group of novel epigenetic drugs and ADCs using technological approaches to tackle ovarian cancer development and progression.

The project is being led by Swansea University with partners Porvair Filtration Group, Bruker UK, GE Healthcare UK, Axis Bioservices and GlaxoSmithKline (GSK). A new Antibody Drug Conjugates company will join the project in its second year.





Principal Investigator Deyarina Gonzalez from Swansea University Medical School adds: "Ovarian cancer is often associated with late diagnosis and poor prognosis meaning new and effective treatment measures are vital.

"The launch of the CEAT project provides an important step in tackling this problem by developing treatments designed to target ovarian cancer cells specifically, sparing the surrounding tissues and limiting the harsh side-effects often associated with chemotherapy. CEAT development platforms will not only provide novel screening tools for selection of lead therapeutic candidates but will also aid the identification of patients that will benefit from these targeted treatments."

Professor Keith Lloyd, of Swansea University Medical School says: ***"The launch of the CEAT project further demonstrates Swansea University's capacity for research and collaboration.***

***"By creating international partnerships with key players in the field of epigenetics and ADCs, the CEAT project is set to make strides in tackling this complex and devastating disease."***

To find out more about Swansea University Medical School visit:  
[www.swansea.ac.uk/medicine](http://www.swansea.ac.uk/medicine)



**Dr Lewis Francis**  
**Nanomedicine Course Director**  
Swansea University Medical School  
Tel +44 (0) 179 260 2716  
[l.francois@swansea.ac.uk](mailto:l.francois@swansea.ac.uk)  
[www.swansea.ac.uk/medicine](http://www.swansea.ac.uk/medicine)  
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# New challenges for public health in the 21st century

Dineke Zeegers Paget, Executive Director of the European Public Health Association (EUPHA) provides a fascinating glimpse of the new challenges for public health in the 21st century

As Europe enters the third decade of the 21st century, we have never been healthier and advances in knowledge and technology have enormously improved our ability to prevent and treat current diseases. Yet there are developments that could, ultimately, threaten the future of humanity. For this article, I will be focusing on five challenges for public health in the coming decades.

The first challenge is the changing demographics in Europe. Climate change, urbanisation, migration and an ageing population are transforming our demographics at the speed of light. For instance, global warming has an increasing impact on migration and we can expect a move to Northern Europe because of economic reasons (e.g. less fertile agricultural land in the South). It is estimated that by 2030, 80% of our citizens will live in urban areas<sup>1</sup> and this may have serious consequences for health if we don't act now.

In addition, the population in Europe is ageing rapidly and we expect the proportion of people aged 65 and older to increase to 25% in 2050.<sup>2</sup> People will live longer, but not necessarily in good health and well-being, thereby increasing the burden on health care systems to treat multimorbidity and chronic diseases. We need to address these changing demographics to mitigate their impact.

The second challenge is the technological and digital revolution. The benefits of technology in health care are clear, developing medical equipment (robot surgery for instance) and better and faster diagnostics (e.g. genetic mapping) are beneficial to prevention and treatment.

On the other hand, there is a real risk in digitalisation. For instance, genetic information can be used in a more discriminative manner for health insurances or

mortgage requests. And even though the digital revolution has given us access to all health information on the internet, the quality of information available is not always in our best interests (fake news).

Finally, technology has also led to new 'diseases', such as gaming addiction, which was included in the 11th International Classification of Diseases of the WHO.<sup>3</sup> We should be aware of the advantages and disadvantages of technology and digitalisation.

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**"It seems clear that the public health network need to adapt to the 21st century challenges. The 21st century public health professional needs to be smart, persistent and creative, be able to be a diplomat and a negotiator at the same time. The approach of health in all policies is essential and the recently published manifesto: 'All policies for a healthy Europe' is a step in the right direction."**

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The third challenge is the political influence on public health, as public health can only be achieved by concerted action at all levels. And to achieve that, we need politics. We need an understanding of the political system and should be willing to work with politicians.<sup>4</sup> Especially now where politics are changing rapidly, populism is on the rise and we see a shift in public opinion on the value of scientific evidence. We need to invest in collaborating and coordinating with politicians to make sure our evidence-based voice is heard.

The fourth challenge is the influence of vested interests. In an era of globalisation, big companies have the power to influence politics as well as research. For instance, the Foundation for a Smoke-Free World describes itself as an independent, private foundation, but is funded by Philip Morris International.<sup>5</sup> Another example is the financial support for numerous health





**Dineke Zeegers Paget**

organisations in Spain by Coca-Cola.<sup>6</sup> But it does not stop there (e.g. food and petrol industry) and we need to find ways to make the collaboration with industry transparent and beneficial to the public's health.

The fifth challenge is the new ethical issues that arise in the 21st century. The right to health, as described in the World Health Organization (WHO) constitution adopted in 1948, includes the right to housing, employment, living standards. But in an era of urbanisation, the right to adequate housing may be nearly impossible to implement. In an ageing population, the discussion between the right to life and quality of life needs to be put on the table, including the right not to live any longer, if the quality of life is decreasing. We need lawyers and ethicists to sit around the table with public health professionals to openly discuss these issues.

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**“It is estimated that by 2030, 80% of our citizens will live in urban areas and this may have serious consequences for health if we don't act now.”**

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It seems clear that the public health network needs to adapt to 21st century challenges. The 21st century public health professional needs to be smart, persistent and creative, be able to be a diplomat and a negotiator at the same time. The approach of health in all policies is essential and the recently published manifesto: ‘All policies for a healthy Europe’<sup>7</sup> is a step in the right direction.

To overcome all the challenges, old and new, we need to:

- Be deliberately collaborative by forging broad alliances in and outside the field of public health to get our messages across;
- Be open-minded to engage with partners, including politicians, to jointly come to solutions that have a broad support base;
- Tell compelling narratives, which address the concerns that people have in a way that people understand; and
- Be transparent and open about potential uncertainties surrounding the evidence-base. ■

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### **Dineke Zeegers Paget**

#### **Executive Director**

European Public Health Association (EUPHA)

Director of the EPH Conference Office

Tel: +31 30 2729 709

[d.zeegers@euphaoffice.org](mailto:d.zeegers@euphaoffice.org)

<https://eupha.org/>

[www.twitter.com/EUPHActs](https://twitter.com/EUPHActs)

# UCL: A global partner for health research & innovation

Jane Kinghorn, along with Marta Ribeiro, Felipe Fouto, and Colby Benari from UCL, argues that the ability to listen and learn makes UCL a global partner of choice for health research & innovation

University College London (UCL) is rightly proud of its strap line “London’s Global University”. With more than 13,000 staff and 38,000 students from 150 different countries, it is one of the world’s leading multi-disciplinary and diverse universities. UCL operates in a global context and are committed to excellence, innovation and the promotion of global understanding in all its activities: research, teaching, learning, enterprise and community engagement.

## Africa

UCL actively works with partners in many countries across the world; and in Africa, UCL is a key academic partner for the [Africa Health Research Institute](#) (AHRI), a multidisciplinary, independent research institute based across two sites in the province of KwaZulu-Natal, South Africa (SA). The goal of AHRI is to become a source of fundamental discoveries into the susceptibility, transmission and cure of HIV, Tuberculosis (TB) and related diseases. AHRI is highly collaborative and works with over 60 academic and clinical institutions across the continent and the world. This made it the perfect choice to partner with UCL’s [Translational Research Office](#) (TRO), [Research Coordination Office](#) (RCO) and [Academic Careers Office](#) (ACO) in applying for and successfully securing, a [UKRI Global Challenge Research Fund](#) Impact Acceleration Award (GCRF IAA).

## GCRF IAA Funding

An aim of the GCRF IAA initiative is to

support cutting-edge research that addresses the challenges faced by developing countries in moving innovation into societal benefit. In 2019, the TRO and ACO organised two events in South Africa, aimed at promoting discussion and sharing knowledge of the challenges faced by innovators, entrepreneurs and businesses in developing products, therapies or interventions, taking into account the local and regional context. Both events were open to participants from across the African continent.

## UCL Workshop in Translational Research, Health Innovation & Commercialization – Durban, SA 19-20th March 2019

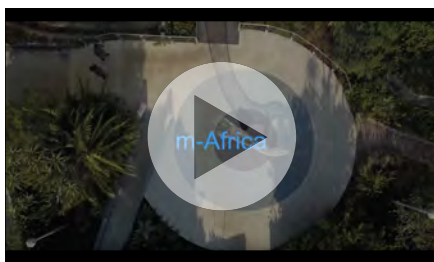
The TRO, in partnership with AHRI and in collaboration with the [University of KwaZulu-Natal](#) (UKZN), organised a two-day Workshop in Translational Research, Health Innovation & Commercialization, which was hosted at the AHRI location in Durban. This two half-day Workshop was targeted at early stage researchers and/or innovators who work in the field of health and life sciences. The aim was to introduce participants to the concepts and tools available to plan the translational pathway of their research towards healthcare delivery and social impact, including discussion around the issues of intellectual property and downstream commercialisation and adoption.

A total of 63 people, both speakers and participants, attended the Workshop

with representation across six African countries (South Africa, Kenya, Uganda, Botswana, Ethiopia and Zimbabwe) and Europe. African participants had affiliations to AHRI, UKZN, [University of Cape Town](#) (UCT), the [Sub-Saharan African Network for TB/HIV Research Excellence](#) (SANTHE) and the [African Academy of Sciences](#) (AAS) amongst others. The event showcased many excellent talks by experienced speakers from a variety of backgrounds in research, innovation, regulation and policy-making and provided an opportunity for multidisciplinary networking and potential future collaborations in the field of health and life sciences. The full programme can be viewed [here](#).

One of the case studies highlighted was m-Africa, a two-year GCRF Global Infections Foundation Award that received funding from the Medical Research Council in April 2017. The aim of the m-Africa project has been to develop low-cost, user-friendly mobile phone-connected diagnostic tools for HIV and evaluate the feasibility of introducing these tools to improve access to HIV testing, as well as linkage to care, in KwaZulu-Natal, SA (please see video). The project is an interdisciplinary partnership between University College London, Imperial College London and the Africa Health Research Institute. m-Africa has also built on technologies developed by the [i-sense](#) EPSRC Interdisciplinary Research Collaboration.

The feedback from the workshop was extremely positive: “Opened a window



of opportunity to make local and international collaboration, which is very important for research development and grant applications." "It provides a fantastic venue to establish intra-African and European-African networks focused on establishing and fostering translational research infrastructure and collaborations." "It gave researchers comprehensive insight into the technology transfer process and the reinforcement from the various organisations was great." "Educating and a pointer in the right direction for doing research and getting research support in South Africa." "The networking opportunity was excellent. The presentation of the TRO as a major resource was extremely valuable."

## **Ignite Medical Innovation Summit – Stellenbosch, SA 26th-27th March 2019**

The Ignite medical innovation summit, organised by the ACO in partnership with the Collaboration for the Advancement of Medical Innovation (CASMI), is an immersive and challenging experience that positions participants to drive change in medical innovation. By bringing together leaders in medical innovation to challenge each other, learn from other's sectors and develop new ways of thinking and working, they will change the future of medical innovation and accelerate progress.

The summit incorporated debate sessions that gave participants a 360-degree view of medical innovation in a discussion format. Further details about each session are available in the summit programme. Speakers from

organisation across Africa and beyond (South Africa, Kenya, Botswana, Madagascar and the UK) led the sessions with the full summit chaired by Professor Sir John Tooke (Chair of CASMI). Participants, also from organisations across Africa, addressed issues that arise when bringing innovations into a healthcare setting. Participants are actively encouraged to maintain the networks forged through the summit and to the wider Ignite Alumni. Some quotes from the summit included:

"Thank you very much for a really informative, thought-provoking meeting. Very well run, expertly chaired."

"It was a pleasure to participate and I look forward to keeping in touch and working with many of the fellow attendees going forward."

## **Future developments:**

Both events highlighted a number of barriers to translation and knowledge exchange across the African continent many of which are shared in developed countries. The level of support for this activity across the continent varies greatly and is nicely articulated in a recent publication (Edwards et.al. Health Research Policy and Systems 2019): "Evidence map of knowledge translation strategies, outcomes, facilitators and barriers in African health systems" Edwards et.al Health Research Policy and Systems 2019 17:16). What we have heard from these debates and discussions is the absolute need to validate assumptions with end users in the field as well as working closely with the government's health policy agenda to invoke solutions into practice. We are now pursuing additional avenues to support innovators and institutes across Africa to further develop their translational support infrastructure tailored to their specific needs.

We wish to thank the UKRI GCRF IAA for providing the funding for the Ignite summit and the UCL Workshop in Translational Research. We would also like to thank our partners and collaborators at AHRI, UKZN and CASMI, for working with us and helping us to organise these events.

Additional authors:

Dr Marta Ribeiro, Senior Business & Innovation Manager, Translational Research Office, UCL

Mr Felipe Fouto, Programme Manager, Academic Careers Office, UCL

Ms Colby Benari, Head of the Academic Careers Office, UCL

Dr Jane Kinghorn, Director Translational Research Office, UCL



**Jane Kinghorn**

**Director**

Translational Research Office, UCL

Tel: +44 (0)207 679 8119

[j.kinghorn@ucl.ac.uk](mailto:j.kinghorn@ucl.ac.uk)

[www.ucl.ac.uk/translational-research](http://www.ucl.ac.uk/translational-research)

[www.twitter.com/ucltro](https://www.twitter.com/ucltro)





# Tailormade tech: The digital primary care solution going further to create automated and localised patient flow

Ben Wood, Director of Operations & Sales at Klinik Healthcare Solutions UK Limited explains how Klinik, is the digital primary care solution going further to create automated patient flow, which is entirely localised

**H**ealthcare tech is a lightning-paced, highly competitive, continuously metamorphosing arena where new advancements and breakthroughs are the lifeblood. Being the latest discovery is the industry zenith but a resounding success in one country that does not denote a triumph in another. This is something being navigated right now by tech wunderkinds, Klinik Healthcare

Solutions. With a user-generated triage solution that assesses, diagnoses and directs patient flow with near-perfect accuracy, their system has been lauded in the home country of Finland.

Now bringing their offering to the UK and consequently the idiosyncrasies of the NHS, their artificial intelligence (AI) technology needs to prove itself as fully flexible too. Used by doctors,

nurses, healthcare specialists and the general public, it's no small undertaking to develop an interface perceived by patients as equal to describing their symptoms to a trusted GP.

"We're incredibly proud of our user input system and we've seen it work in 300 clinics across Finland to reduce waiting times and optimise efficiency but we're all too aware our offering

has to convert into different markets,” says Petteri Hirvonen MD, Chief Medical Officer at Klinik Healthcare solutions. “The UK and Finland have many similarities but they’re by no means identical, so it’s not an off-the-shelf situation. The technology is first class, we know this, but it’s only a success if it works in real-life situations, for real people.”

This is why Klinik have been so painstaking in their trialling within NHS organisations. With a game-changing AI offering able to help nurses make more informed, confident decisions about patient care without relying on GP support and encourage patients to use self-service triage to remove pressure from frontline practice staff, it was crucial to find a platform to test and tailor their offering to the UK market. Enter Kernow Health CIC’s ‘Sandbox Approach’, offering companies a way to sample and improve their products in real-life NHS clinical environments. By linking tech companies directly with practising medical teams, the initiative speeds up and simplifies this validation process so doctors, support staff and patients alike can start benefitting from new technical solutions sooner.

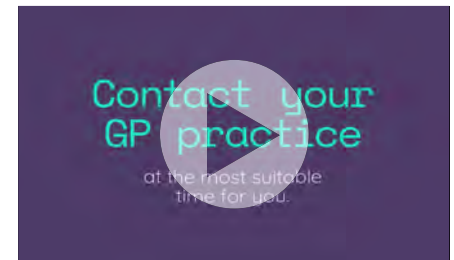
An initial collaboration with the University of Plymouth produced a series of workshops with leading research teams gleaning insight into how to make Klinik’s AI offering even more bespoke to the UK market and the NHS. As an extensive research centre for emerging healthcare technologies, the team at Plymouth University offered crucial feedback to Klinik in how NHS doctors are trained to work in the community. “Gaining an academic perspective from the University of Plymouth’s Centre of Health Technology

(CHT) has been of great benefit,” explains Hirvonen. “We asked them to map out the current processes in three GP practices so that we could gain a better understanding of how they currently organise triage and therefore how digital triage could be best deployed.”

**“Healthcare tech is a lightning-paced, highly competitive, continuously metamorphosing arena where new advancements and breakthroughs are the lifeblood. Being the latest discovery is the industry zenith but a resounding success in one country that does not denote a triumph in another.”**

Klinik then went onto work with the three GP surgeries across the South West to live-test its adapted product. All practice staff and patient test groups were given free-reign with the user interface to evaluate. Aspects, such as symptom input, urgency detection, decision support and an online messaging system whereby staff can communicate with patients in real time where all analysed in-depth for user experience.

“What’s so positive about this process is we couldn’t have predicted the findings,” explains Ben Wood UK Director of Operations & Sales at Klinik. “Of course, we were thrilled to hear how positive the feedback was but even more useful, were the critiques. Key learning for us was in communicating wait times. Our Finnish model has them as a generic standard but NHS GP staff asked us to go one step further and have an option for them to set their own wait times that patients could see and, therefore, manage their expectations. This is something that for us is a minor



update but will make a considerable difference for NHS medical professionals and their patients.”

Working on a global platform is today’s industry standard but as Klinik is appreciating, the blanket approach is not an effective model. Technology can span continents but only if carefully translated to that region’s unique characteristics. Healthcare systems are so acutely location-centric that any tech model must be agile enough to translate seamlessly to each local market. Enter the new era of being global-local; for the healthcare tech industry at least, it certainly seems the brightest way forward.

**KLINIK  
HEALTHCARE  
SOLUTIONS**

**Ben Wood**

**Director of Operations & Sales**

Klinik Healthcare Solutions UK Limited

Tel: +44 (0)7817 287 834

ben.wood@klinik.fi

www.klinikhealthcaresolutions.com

# Health: The priorities of the European Commission

The priorities of Vytenis Andriukaitis, the current European Commissioner for Health & Food Safety are explained here, with the examples of antimicrobial resistance, big data and transparency to support science and innovation, amongst others

**V**ytenis Andriukaitis is the current European Commissioner for Health & Food Safety and his responsibilities cover national health systems and food safety. On the former, his responsibilities include helping to deal with the challenge of increased calls on national health services during intense pressure on public finances. He is also responsible for building up knowledge on how [national health systems](#) to shape national and European Union (EU) policies are performing. Here, we'll focus on these public health aspects of his remit, including big data, tackling antimicrobial resistance and support science and innovation.

## Health promotion, education and disease prevention

On public health, one striking development took place on 19th February, when Commissioners Andriukaitis and Crețu brought together health professionals to kick-start the reflection on future EU investments in health that fall under the 2021-2027 Cohesion Policy programmes. The roundtable discussion on that day concluded that health systems are moving towards more health promotion, education and disease prevention. There is a shift away from hospital and institution-centred care to community-based care and a move to the integration of health and social care.

In this vein, Commissioner for Health and Food Safety, Vytenis Andriukaitis, shares his thoughts: "According to the most recent Eurobarometer survey, almost 70% of Europeans want the EU to do more in the area of health. Acting via Cohesion Policy funds offers us the possibility to make a difference on the ground where it is needed and show that the demands expressed by fellow Europeans are not left unheard. I am also delighted that health becomes a new category for the

RegioStars. This is yet another demonstration that we must and can implement the principle Health in All Policies as set out in the Treaty."<sup>(1)</sup>

## Tackling antimicrobial resistance (AMR)

In late 2017, Commissioner Andriukaitis outlined the EU's '[One Health' approach](#) to tackling antimicrobial resistance and it is here that he points out the misuse of antibiotics in people leads to antimicrobial resistance (AMR) – a growing challenge which at the time of writing was responsible for 25,000 deaths in the EU every year. To deal with this, we find out that the EU pushed forward a 'one health' approach to deal with AMR, "taking concrete actions in human and veterinary medicines simultaneously", as the Commissioner puts it. Cooperation and coordination are crucial aspects for this policy to work, so that together with international bodies such as the WHO, OIE and FAO, progress can be made in tackling AMR with, "a one planet, one voice and one health approach."

In more recent news, we learn about the "Strategic Approach to Pharmaceuticals in the Environment" presented on 11th March, which identifies six action areas on all stages of the pharmaceutical life cycle, in an effort to seek improvements. Commissioner Andriukaitis's comments on this which draw our attention to the issue of AMR.

"It is essential that medicines are safe and effective for our health, however we should be aware of the environmental impact they may have. Drug-resistant bacteria is one of the major health threats world-wide, therefore in our fight against antimicrobial resistance, everyone benefits not only from the prudent use of medicines but also from a well thought-through



production and disposing system. It is time for us collectively to draw attention to the risks of the antimicrobials for the environment. This Communication identifies areas where action is needed and serves us as a stepping stone for our future discussions.”<sup>(2)</sup>

### Big data

In the April 2019 edition of Open Access Government, we uncovered one prominent theme of Commissioner Andriukaitis that concerns big data. In his view, big data, “has the potential to unlock important new prevention, diagnostic and therapeutic avenues”. While innovation is now linked even more with the use of big data, challenges in this area remain, Commissioner Andriukaitis believes. Commissioner Andriukaitis also explains his increasing acceptance of big data, a fascinating point he details in his own words.

“Whether it be pools of sequenced genomes, or real-world environmental and lifestyle data, it is clear that access to larger samples will facilitate more effective, deeper, more targeted research.

“The need to share relevant data more broadly led to the launch of the European Open Science Cloud. This pilot project is funded by Horizon 2020 and is a big data demonstrator scheme. It includes pan-cancer analyses to identify common mutation patterns for better care.”

### Transparency to support science and innovation

Finally, let’s look at one aspect of the Commissioner’s remit that concerns the importance of transparency when it comes to science and innovation related to public health. One point Commissioner Andriukaitis underlines is that there is delicate balance to be struck to ensure research and development is incentivised while ensuring that innovation is meaningful to patients remains affordable so that the whole of society can access it of society. In his late 2018 speech, the Commissioner explains his thought on this in more detail.

“Bringing more transparency on the full cost of Research & Development would help guide the current debate on how improvements can be found in the current R&D model. Increasing transparency is an important part of the EU’s new Clinical Trials Regulation, which is expected to apply from 2020.”

Having said that, Commissioner Andriukaitis said that this is not enough and here, therefore, urged: “A fluid and continuous exchange of information between payers and the industry is essential throughout the R&D phase as well as the subsequent processes of authorisation and health technology assessment.”<sup>(3)</sup>

One area that the European Commission has been supporting concerns brain research, which they have supported over the years through their Framework programmes. Through these investments, at a better understanding of brain function and dysfunction, developing methods for diagnosis and monitoring, prevention, treatment as well as care and support is the intended aim.

One project the European Commission supports is the Human Brain Project (HBP), that sets out to give a cutting-edge, ICT-based scientific Research Infrastructure for brain research, brain-inspired computing and cognitive neuroscience. In addition, the Commission also fosters encourages cooperation among EU Member States through the EU Joint Programme – Neurodegenerative Disease Research (JPND), the largest global research initiative that tackles neurodegenerative diseases.<sup>(4)</sup> ■

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# The future of artificial intelligence in health

The future of artificial intelligence in health is placed under the spotlight here by The Alan Turing Institute, UK

**A**rtificial intelligence (AI) will have a profound, positive and transformative impact on the health of European and worldwide populations. There is huge interest and worldwide investment in general AI, and health systems are one of the most important application areas. Europe is uniquely placed to play a leadership role in the race to build better, more accurate and safer health technology systems through the use of AI. European researchers are at the forefront in the development of safe, robust and effective AI delivering substantive patient and public benefit.

If properly managed, AI research will deliver both sustained health improvements as well as economic benefits to Europe. It will give our clinical and health researchers the time to focus on what they do best, enhancing their skills and maximising their expertise by augmenting their activities through AI systems that provide pertinent and timely information and reduce the burden from more mundane tasks<sup>1</sup>.

However, in order to reach this potential and for Europe to lead in this field, we need to address five key challenges. Policymakers should focus their attention on delivering these.

**1. Data as infrastructure** – “getting the learning base right”. AI algorithms are ravenous for data. It has been said that if AI is a rocket then data is the fuel. Data fuel is needed both in high volume

and high quality. Poor quality data leads to systems that underperform.

Any AI system is only as good as the underlying learning base as, once trained, an AI algorithm is simply a mathematical compression of the data that it learned from. In addition to data quality, AI systems inherit any systematic or sampling bias present in their training data. For example, AI models using genetic information for disease risk prediction may be prone to bias or loss of performance unless trained on biobanks that are fully representative of population diversity of ethnicities. We must ensure that the less well-off are represented in the learning bases. This being especially true of genetics, where we often see an under-representation of non-European recent ancestries.

The learning base is the critical first component of any AI system and, as such, it is imperative that governments invest in European federated learning bases, connecting up health data at scale that can allow algorithms to train most effectively across all representatives of society. We need to ensure we have captured the full diversity of population data that will be encountered in the real world or, if not, have in place the necessary validation procedures to ensure that learned algorithms are robust in their conclusions (see below).

Within the UK, [Health Data Research UK](#) (HDR UK) are tackling this problem

head-on. As Professor Morris, director of HDR UK notes: “The UK has some of the most renowned data sources internationally, from NHS data to clinical trials, world-leading cohort studies and social, molecular and environmental data. Our ambition is to revolutionise research and innovation in the UK by working in partnership to enable linkage, access and analysis of these health data at scale and in a trustworthy way.”

Spearheading this is a series of [Digital Innovation Hubs](#) as exemplars of the technical and analytic challenges that lie ahead.

**2. Public and patient engagement** – “listen, learn and deliver benefits back to the people”. If AI is to transform European health services, we must bring the public with us along the journey. Public concerns regarding privacy and use of their health data for commercially driven activity are genuine and prescient. Important recent developments that need to be pursued include “algorithmic fairness” and “explainable AI”, the former ensuring that AI-based recommendations do not discriminate across key characteristics, such as race and gender and the latter building systems that provide interpretable recommendations.

**3. Engineer robust solutions** – “reproducible performance and validation of systems from bench to bedside”. Health data systems need to be robust and trustworthy. Due to the opaque nature of many AI algorithms, such as deep learning used for medical imaging diagnosis, the validation of such systems is more nuanced than testing traditional computer programs where formal system checks can be implemented. Care is needed in the design of AI validation protocols.

These protocols need to be explicit, auditable and in place at the study design phase and prior to the training of the algorithms. “Reproducible research”, whereby external partners can rederive claimed performance results is essential and will need to become a mantra of health systems AI. The Alan Turing Institute in partnership with UK and international partners have been developing guidelines in this respect<sup>2</sup>.

In engineering solutions across Europe, AI systems are being developed in the leading hospitals by the leading researcher units using the best measurement technologies. We need to understand how performance is affected when moving from state-of-the-art research labs to real-world clinical settings, such that we design systems to be robust with well characterised and trusted performance measures.

**4. Regulation** – “delivering safe algorithms”. Ensuring that algorithms meet pre-defined acceptable levels of performance and safety guarantees, with smooth degradation of performance if applied to new environments requires new policy. Current regulatory procedures for software in medical systems are based on an assumption of static, explicit, code. Yet, by their very nature, machine learning systems are designed to improve their performance through continuous exposure to data. For continuous learning systems, we will need effective measures for monitoring and updating and clear, auditable requirements when systems go wrong.

**5. Invest in the foundations** – “why it works”. Modern AI is in its infancy, driven by an explosion of data captured at scale coupled to computers now able to process the vast number of

numerical computations needed to train new classes of models. AI has shown impressive, game-changing, empirical performance but we still have little understanding of the theoretical foundations of why AI works so well and where it might be prone to brittleness. There is a danger of building our AI house on the sand. Fortunately, Europe is home to some of the leading computer scientists and computational statisticians working on the foundations of AI. We have seen recent investment in national institutes, such as The Alan Turing Institute in the UK and the Finnish Centre for AI that are addressing fundamental research in AI. These centres are providing a focus for researchers developing the core principles and new algorithms for machine learning at scale<sup>3</sup>. Europe must join together to combine our strengths.

The newly established European Laboratory for Learning and Intelligent Systems (ELLIS) is a prime example of how Europe can lead alongside our international partners. In the words of Bernhard Schölkopf, director at the Max Planck Institute for Intelligent Systems and co-founder of ELLIS: “Applications of AI are changing our lives and these changes originate from centres where the best research is done. Europe should play an active role in supporting fundamental research in machine learning in order to influence this transformational process. ELLIS will ensure that such research is performed in and shaped by the open societies of Europe to deliver the benefits of AI to all.”

If Europe invests in these five areas then the future is bright. New algorithms will have access to open, secure data learning bases, representative of European societies. The public will be informed and kept abreast of the benefits that accrue from donating

health data at the population scale. Engineering principles and regulatory protocols will provide clear guidance to AI researchers and AI start-ups on the path needed to take ideas from concept to deployment in the clinic. The leading AI research labs, connected and enhanced through structures such as ELLIS, will provide the foundations underpinning all such developments and bring on the next generation of young research leaders and disruptive AI technologies that will drive forward improved health outcomes. If we succeed in this endeavor then the potential to improve health for all Europeans will be dramatic.

Professor Holmes is Scientific Director for Health at The Alan Turing Institute, the UK’s national institute for AI and data science and chair in biostatistics at the University of Oxford. His work is supported by Health Data Research UK, the Li Ka Shing Foundation, the Medical Research Council UK and EPSRC UK.

<sup>1</sup> Deep Medicine. (2019). Eric Topol

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**The Alan Turing Institute**

**Chris Holmes**  
**Professor**

University of Oxford, and  
The Alan Turing Institute  
Tel: +44 1865 285874  
[chris.holmes@stats.ox.ac.uk](mailto:chris.holmes@stats.ox.ac.uk)  
[www.stats.ox.ac.uk/~cholmes/](http://www.stats.ox.ac.uk/~cholmes/)



# FLEXPOL: An antimicrobial adhesive film

The EU-funded project FLEXPOL (GA number 721062) offers an affordable approach to prohibit the spread of bacteria and healthcare-associated infections using cost-effective and sustainable film products

Healthcare-associated infections and diseases induced by multi-resistant bacteria are causing significant numbers of deaths each year within the European Union (EU). To overcome this problem, the FLEXPOL project is developing a low-cost antimicrobial adhesive film to prohibit the spread of bacteria in hospital environments. This product offers a flexible, sustainable and scalable solution to lower the risk of healthcare-associated infections.

## Multi-functionality – The interdisciplinary FLEXPOL approach

The FLEXPOL film consists of a three-layered base-material and is made of safe and economical polypropylene (PP). While the outer layers of the film are made from a PP material with a very high stiffness to provide maximum abrasion resistance, the inner layer is made of a PP grade, which is suitable for the introduction of active substances into the film.

Essential oils are incorporated into the inner layer which are able to penetrate the outer polymer surface. As some essential oils are known to have an antimicrobial effect, the release of these oils to the surface of the film will kill bacteria. Due to the fact that essential oils are extremely volatile substances and potentially able to

cause allergic reactions, the release must be precisely controllable. To achieve this, the active chemicals are encapsulated into  $\beta$ -cyclodextrin matrices, which is a special form of carbon-hydrates. The encapsulation and subsequent introduction of the active substances into the polymer matrices allows a stable, controlled release of chemicals, giving the FLEXPOL film a functional life of about six months.

The surface of the FLEXPOL film is characterised by an innovative micro-nano-structure. The combination of micropillars and nanospikes (black silicon) causes very high water contact-angles. This results in highly hydrophobic behaviour and creates a 'lotus effect' on the surface. As bacteria need a medium to grow, the absence of water effectively prevents the microorganisms from growing and spreading over the surface. Even before adding the oils to the inner layer, it was already proven that the structure alone has strong antimicrobial characteristics and was able to reduce an initial number of *Escherichia coli* (*E. coli*) bacteria by 90% within 90 minutes.

Further testing was done with *Staphylococcus aureus* – bacteria which offer a potentially high-risk for healthcare-associated infections, due to an

increasing percentage of methicillin resistant strains. Even though these bacterial strains are highly resistant, the FLEXPOL film effectuates a high degradation rate in a short period of time.

The combination of both approaches leads to a product, which on the one hand is able to suppress the attachment and growth of bacteria on the covered surface by the topography and on the other hand actively kills bacteria by the introduced essential oils.

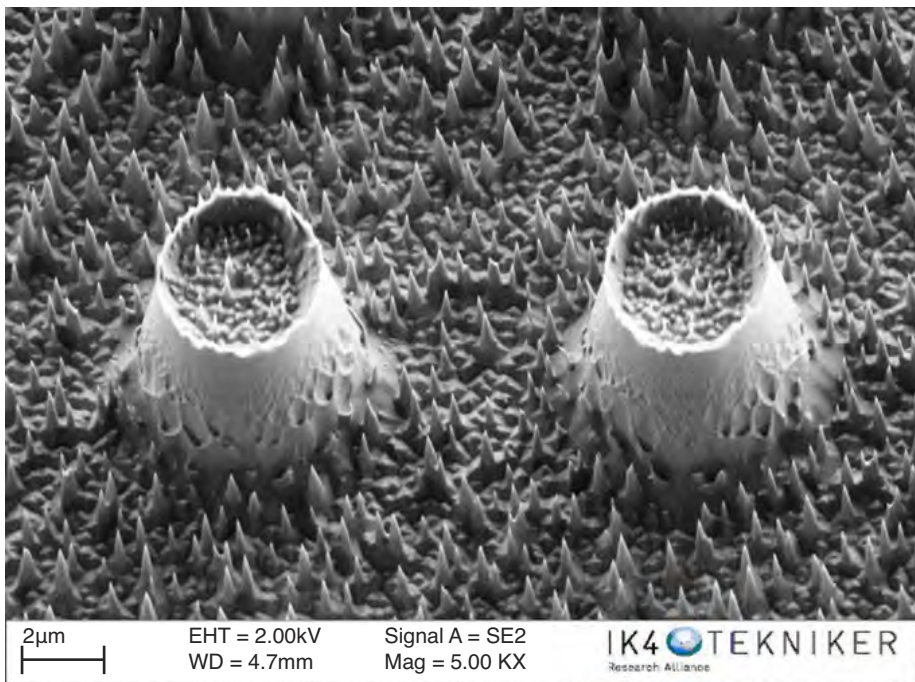
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**“The goal of the FLEXPOL project is to invent a highly functional material, combined with a low-cost production process in order to make it affordable for everyday applications.”**

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## Sustainability – The environmentally friendly and safe use of the FLEXPOL film

In comparison to state-of-the-art antimicrobial film products, the FLEXPOL approach offers significant advantages. Most commercially available antimicrobial films rely on active nanoparticle substances like silver-ions. However, the consequences of nanoparticle deposits once they enter the human body is not fully proven yet. The raw-material polypropylene used in FLEXPOL's film however, is the same as that used in food-packaging applications. The active substances,



*Micro-nano-structure of the FLEXPOL film*

vaporising from the film are essential oils from natural resources like oregano or thyme. In order to prove any potential risks of the FLEXPOL film, cytotoxicity tests were carried out frequently during the course of the project. None of the tested combinations of topography and active substances showed cytotoxic behaviour in the in-vitro tests. Thus, the film can be considered as a safe-to-use material.

### Scalable solution – The key-enabler for everyday use

The goal of the FLEXPOL project is to invent a highly functional material, combined with a low-cost production process in order to make it affordable for everyday applications. The applied polypropylene grades for film production are commercially available and extruded in a blow-extrusion process,

capable of throughputs of hundreds of meters per hour. Subsequently, the hierarchical surface structures are introduced by a roll-to-roll hot-embossing process, offering a high-throughput without the need for additives like UV-curable resins. For large-scale production, the costs of the FLEXPOL film have the potential to almost decrease to the costs of just the raw materials. This is a key enabler to make it affordable as a standard solution in hospitals.

### Readiness – How close is the FLEXPOL film to the market?

The FLEXPOL project (EU-funded until December 2019) is currently in a pre-market state. Certainly, the anti-microbial efficiency has been validated in-vitro and the production process has been successfully implemented. A final validation in a hospital environ-

ment will show the efficiency of the film in real-life conditions. The complete production process is carefully traced and documented by a shared database, in order to enable the targeted certification as a class-one medical device.

“The surface of the FLEXPOL film is characterised by an innovative micro-nano-structure. The combination of micropillars and nanospikes (black silicon) causes very high water contact-angles. This results in highly hydrophobic behaviour and creates a ‘lotus effect’ on the surface.”

 **Fraunhofer**  
IPT

**Maximilian Kosel**  
**Project Manager**  
Fraunhofer Institute for  
Production Technology  
Tel: +49 241 8904 270  
maximilian.kosel@ipt.fraunhofer.de

**Thomas Scheuer**  
**Project Manager**  
Fraunhofer Institute for  
Production Technology  
Tel: +49 241 8904 366  
thomas.scheuer@ipt.fraunhofer.de

# Vessel growth in health and disease

John Greenwood PhD FRCPATH and Stephen E. Moss PhD from UCL Institute of Ophthalmology discuss the vasculature in health and disease, a major focus of their research

The human vasculature is an exquisite hierarchical system that is responsible for the delivery of blood to every organ of the body. Adult humans are estimated to have almost 100,000 km of blood vessels, with the bulk of this impressive figure coming from small microvessels that permeate throughout the tissue where they exchange gases, nutrients, waste products and immune cells with the local environment.

During development, blood vessels grow through angiogenesis to serve the needs of the expanding tissue, a process that has been studied extensively and that has illuminated the key signalling molecules and pathways involved. New vessels also undergo a process of stabilisation and maturation that confers physiological function according to their hierarchical position and the requirements of the organ in which they lie. Once mature they provide a selective and regulatory barrier between the circulating blood and the tissue.

The vasculature has a remarkable capacity to maintain its function throughout life but, not surprisingly given its ubiquitous presence, it is also involved in many major diseases. Vascular dysfunction may manifest in a number of different ways including barrier breakdown leading to fluid leakage (oedema) and bleeding (haemorrhage), vessel degeneration or blockage (stroke) resulting in oxygen deprivation (ischaemia) and the uncontrolled growth of abnormal new vessels (neovascularisation). These

defects may be the primary cause of the disease, or a secondary consequence of another disease process, but in both cases vessel dysfunction is highly damaging.

## New vessel formation in disease

Blood vessels that grow in diseased tissue are nearly always abnormal; forming a chaotic vascular network that leaks fluid, is susceptible to rupture, and poorly perfused, characteristics that contribute to progression of the particular disease. Archetypal amongst these conditions are the solid cancers and retinal diseases including neovascular (or wet) age-related macular degeneration (nAMD) and proliferative diabetic retinopathy (PDR).

It has been known for many decades that solid tumours are able to stimulate new vessel growth to support their expansion. Indeed, it has been postulated that cancers cannot grow much larger than a few millimetres diameter without this happening (Folkman 1971). Whilst this view has been somewhat modified in recent years, as some cancers can utilise existing vessels, this general principle still holds true. For most of the last century, therefore, the prevailing opinion has been that if new vessel growth could be inhibited then this would constrain tumourigenesis.

As mentioned above, a great deal is known about the factors responsible for driving developmental angiogenesis and it is clear that the same key factors are also responsible for mediating neovascularisation in cancer. Principle

among these is vascular endothelial growth factor (VEGF) and its signalling partners that are induced in the absence of oxygen (Apte et al 2019). Some 15 years ago a biologic (antibody - Bevacizumab) targeting VEGF underwent clinical trials in cancer and its use has had some success in increasing progression-free survival in certain cancers, although with little impact on overall survival rate.

Nevertheless, in a wonderful example of opportunism, bevacizumab was demonstrated to be highly effective in blocking new vessel growth in sight-threatening ocular diseases, most notably nAMD, and more recently in PDR. Nonetheless, many patients remain refractory to VEGF axis blockade illustrating a continued unmet clinical need.

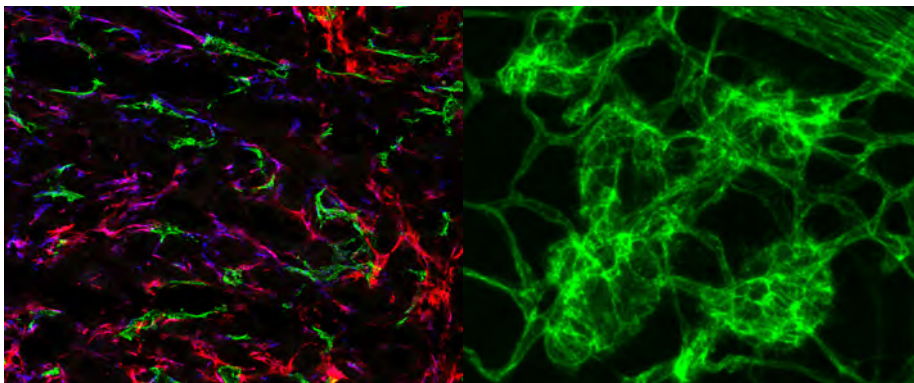
What has been highlighted by these vascular targeted approaches is that there is still much that we don't understand about pathological neovascularisation.

For example, angiogenesis can escape from the influence of the prototypical drivers and, in different disease settings, control of vessel growth is clearly finely nuanced. With a growing appreciation of the role the vasculature plays in human disease it is therefore critical that new targeted therapies are developed to treat those conditions that remain non-responsive.

## Development of drugs that target new vessel growth

There continue to be advances in





*Left image: Blood vessels (green) and vessel support cells (mural cells – red and blue) in a model of pancreatic cancer. Right image: Abnormal vessels in model of retinal vascular disease.*

developing drugs that target the VEGF axis and related pathways, but other targets need to be identified and new therapies developed. Recently great interest has arisen surrounding the role of metabolism in regulating vessel growth (Potente & Carmeliet 2017). Perhaps not surprisingly, as in oxygen deprivation, paucity in the supply of essential metabolites is a trigger for new blood vessel growth. It is likely to be only a matter of time before new therapeutic approaches based on this knowledge will become mainstream.

In our own laboratory, work funded by the Medical Research Council (UK), the Wellcome Trust, the British Heart Foundation and University College London Technology Fund, led to the identification of a novel therapeutic target, leucine-rich alpha-2 glycoprotein-1 (LRG1) (Wang et al 2013). Unlike the VEGF axis, this secreted molecule is not involved in developmental angiogenesis but is only induced in diseased tissue where it corrupts the normal angiogenic process. This discovery may explain why blood vessels grow abnormally in disease.

Interestingly, in cancer there is a growing view that rather than destroy abnormal tumour vessels or inhibit their growth, it may be more appropriate to improve their function; a process termed vascular normalisation (Jain 2015). This is predicated on

evidence that an inadequate blood supply is both pro-oncogenic and limits the delivery of therapeutics. In laboratory studies we have found that blocking LRG1 improves vascular function and the delivery of other tumour drugs. Based on our findings we have developed a therapeutic antibody (Magacizumab) and clinical trials in ocular neovascular disease and cancer are planned through the support of UCL Business and the formation of a spin-out company.

## The future

Therapeutic targeting of the vasculature is likely to be of increasing importance in the treatment of many diseases and with personalised medicine and greater use of combinatorial drug approaches the outlook is promising. However, many obstacles lie ahead not least of which is the challenging funding landscape and the possible damage to cross-EU research threatened by Brexit. Laboratories throughout Europe have made, and will if given adequate support, continue to make a substantial contribution to our knowledge in this field. Governments and funding agencies must therefore be prepared to invest long-term in both fundamental discovery science in this area as well as translational proof of concept research.

As it can take the best part of 15 years to go from target discovery to clinical

trials long-term strategies are essential. It is recognised that the attrition rate along the road to delivering new treatments is high but the rewards, both in terms of health and wealth, are considerable. For example, the tens of millions of people worldwide diagnosed with cancer, nAMD and PDR each year will benefit, and with the market value of anti-VEGF therapies alone in these diseases currently ~\$10 billion per annum it is incumbent on the European governments to ensure that there is adequate investment in this area.

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**John Greenwood PhD FRCPATH**  
**Davson Professor of Biomedical Research**  
 UCL Institute of Ophthalmology  
 Tel: +44 (0)207 608 6858  
[j.greenwood@ucl.ac.uk](mailto:j.greenwood@ucl.ac.uk)  
[www.twitter.com/greenwoodjohn](https://www.twitter.com/greenwoodjohn)  
<https://iris.ucl.ac.uk/iris/browse/profile?upi=JGREE74>

**Stephen E. Moss PhD**  
**Ashton Professor of Biomedical Research**  
 UCL Institute of Ophthalmology  
 Tel: +44 (0)207 608 6973  
[s.moss@ucl.ac.uk](mailto:s.moss@ucl.ac.uk)  
[www.twitter.com/stephenemoss](https://www.twitter.com/stephenemoss)  
<https://iris.ucl.ac.uk/iris/browse/profile?upi=SEMOS35>

# Addressing gaps in systemic lupus erythematosus management

Lupus is on the rise, yet awareness of the disease remains relatively low. However, efforts are underway to tackle existing gaps in managing the condition, as we discover here, as well as the European Commission's strong support for rare diseases more generally

According to Versus Arthritis, [lupus is an autoimmune disease](#), which basically means that the immune system produces antibodies that attack the body's own tissues, causing inflammation. The two main types of lupus are discoid lupus and systemic lupus erythematosus (SLE) – the focus of this article will be on the latter.

By way of introduction, we know that systemic lupus erythematosus (SLE) is the most common form of lupus, affecting approximately 70% of the estimated 5 million people with lupus worldwide.

SLE is a chronic, incurable autoimmune disease that affects many organs and systems of the body, including the skin, joints, lungs and kidneys.

SLE is more common in younger people; only about one in 15 cases begin after the age of 50. It is around nine times as common in women as in men and is more common in women of Chinese, African and Caribbean origin.

The signs and symptoms of SLE vary but can include

extreme fatigue, malaise, joint and muscle pain. A red “butterfly” rash across the cheeks and bridge of the nose is also a characteristic feature of the disease.

Around a third of people with SLE develop the kidney disease nephritis. Heart problems can also occur, including inflammation of the membrane around the heart and abnormalities in the valves that control blood flow.

In addition, inflammation associated with SLE can damage the nervous system and cause seizures, stroke and difficulties with processing, learning and remembering information.

People living with SLE experience periods of exacerbation and remission but over time, SLE gets gradually worse and damage to the major organs can be life-threatening.

Anxiety and depression are commonly associated with SLE. Indeed, a global survey by the World Lupus Federation to mark World Lupus Day on 10th May this year found that the psychological impacts of the disease can be as devastating as the physical. Nearly two-thirds



of respondents (61.6%) said living with SLE had a major impact on their emotional and mental wellbeing.

Another report released to coincide with World Lupus Day warned that although progress has been made in managing lupus, there is still a lack of awareness about the condition among both the general public and healthcare practitioners, which can lead to people with lupus feeling misunderstood, isolated and alone. In one global survey, 51% of respondents did not know lupus is a disease.

The report, *A Vision for Lupus*, published by pharmaceutical firm GSK, included three “calls to action”:

1. Raising awareness of lupus among the public, people living with the disease, their families and healthcare providers to achieve early diagnosis and help people with lupus to feel more acknowledged, understood and supported.
2. Improving access to specialist and multidisciplinary lupus clinics to ensure quality care that addresses all aspects of the disease.

3. Raising awareness of ongoing clinical trials, encouraging people with lupus to consider taking part in research and facilitating easier access to these trials. In turn, people with lupus should be empowered to make autonomous decisions about managing their condition.

The report concludes that the increasing prevalence of lupus indicates it is no longer a rare disease. It is, therefore, more important than ever to address the gaps in its management. ■

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# MASTERPLANS to Disentangle the Complexity of Systemic Lupus Erythematosus (SLE)

Professor Ian N Bruce MD FRCP, Professor of Rheumatology at the University of Manchester shares his expertise here on Systemic Lupus Erythematosus (SLE), a chronic multisystem autoimmune condition

In the past 60 years, only one drug has been approved for the treatment of SLE. As a result, there is a huge unmet need to address the poor long-term outcomes and ongoing dependence on chronic steroid therapy in this patient group. A UK-wide consortium led from The University of Manchester is trying to disentangle the complexity of this condition and to define patient subgroups that will derive particular benefit from treatments which are in routine use or which may have 'failed' in previous clinical trial programmes.

Systemic Lupus Erythematosus (SLE) is a chronic multisystem autoimmune condition that can affect a range of organs and tissues, including the joints, skin, kidneys and brain. SLE affects one in 4,000 individuals in the UK and has a strong (10:1) female: male preponderance. It is also much more common in patients of African, Indo-Asian or Chinese ancestry. As well as higher rates of mortality, SLE patients also have an excess risk of many long-term complications including premature coronary disease, infections, renal failure, osteoporosis etc. A number of these complications are related to ongoing active disease. Others are associated with chronic exposure to glucocorticoids which remain a frequently employed therapy in SLE.

Current approved treatments for SLE remain limited and include anti-malarial drugs, glucocorticoids and conventional immunosuppressives, most of which are used 'off label'. This is because, since 1959, only one drug (belimumab -Benlysta) has been licenced for the treatment of SLE. Overall, the treatment used is selected based on a doctor's experience and often on a 'trial and error' basis. Standard immunosuppressives such as mycophenolate mofetil (MMF) have had response rates of 50-60% in clinical trials. Newer biological therapies such as rituximab and belimumab, whilst targeted at specific immune processes, again report response rates in trials of 40-60%. As a result, many patients have persistent 'grumbling disease' due to inflammation not being adequately controlled and require ongoing glucocorticoid therapy; many of the long-term complications in SLE patients are related to these factors.

An MRC-funded UK consortium is helping to address a number of these challenges by taking a novel 'stratified medicine' approach to the treatment of SLE. Following a model established in a number of other conditions, the **MAXimizing SLe THERapeutic Potential by Application of Novel and Stratified approaches (MASTERPLANS)** consor-

tium is led from the University of Manchester by Professor Ian Bruce, Professor of Rheumatology. The consortium includes nine UK Universities, 10 industry partners with significant input from patient collaborators in association with Lupus UK, the national patient charity for this condition (Figure 1).

To do this, the MASTERPLANS consortium is focused on identifying predictors of response to particular lupus therapies. Working with partners in the pharmaceutical industry, the consortium is re-analysing data from previous lupus clinical trials and also analysing data already available from a number of cohorts studies in the UK and internationally. From these studies, we are beginning to identify factors that predict response or improvement in SLE. An important aim is to determine which factors predict improvement in SLE in general and which are related to a specific treatment regime. A strong team of statisticians and methodologists are working in the consortium to address these challenges.

The other major programme of work is taking advantage of data collected over the past nine years in the British Isles Lupus Assessment Group Biologics Register (BILAG-BR). The BILAG-BR is

MAXimizing Sle ThERapeutic Potential by Application of Novel and Stratified approaches (MASTERPLANS) Consortium		
Academic Partners	Patient Collaborators	Industry Partners
University of Manchester University of Leeds University of Birmingham University College London Imperial College London King's College London University of Bath Cambridge University University of Liverpool	Lupus UK	GSK UCB Roche/Genentech Medimmune Aurinia Pharma Pfizer Epistem Aeirtec Myriad RBM Imagen-Biotech

Figure 1: MAXimizing Sle ThERapeutic Potential by Application of Novel and Stratified approaches (MASTERPLANS) Consortium: an MRC-funded Stratified Medicine Consortium for Systemic Lupus Erythematosus

UK-wide prospective observational cohort study assessing the long-term safety and effectiveness of new treatments in SLE. This register has recruited over 1,100 SLE patients with regular follow-up and in whom blood samples have also been collected and stored. These samples will be used to look in detail at how circulating factors ‘biomarkers’ can improve prediction of response beyond that possible with information routinely collected in clinics.

The results of both work-streams will be combined and used to identify factors for validation in clinical trials towards moving them into the clinic to inform more personalised therapeutic decisions. Through all these studies is a parallel work-strand studying the economic costs of lupus to the health care system, as well as indirect costs of lupus to the individual and society. This will give clear information on

which to base future decision-making and to ascertain whether any innovative biomarker or algorithm improves the cost-effectiveness of caring for SLE patients.

Looking to the future, the MASTERPLANS consortium is actively seeking to work with other groups focused on precision medicine in SLE. As part of our longevity plan, we are also seeking to add partners and datasets to our consortium to explore novel stratification factors for other therapeutic agents.

Disentangling this challenging condition and taking a precision medicine approach to SLE will help us control the disease better, improve survival rates and reduce the overall need for steroid treatment. Such an approach will also be a model for future clinical trial development in SLE and may help repurpose apparently ‘failed’ treat-

ments. Treating the right patient with the right drug from earlier in their disease course will significantly improve the quality of life for lupus patients whilst also providing financial saving for the healthcare and benefits systems.



**Professor Ian N Bruce MD FRCP**  
**Professor of Rheumatology**  
 University of Manchester  
 ian.bruce@manchester.ac.uk  
 @Lupusdoc

# The development of precision medicine and biobanking initiatives in the Russian Federation

In this insightful article, experts highlight recent developments in the field of precision medicine research and biobanking infrastructure in Russia, boosting national biomedical research programmes and facilitating integration into global research networks

The rapid technological development has been a major contributor to the progress of precision medicine initiatives globally. The Russian Federation is no exception and has been supporting such national initiatives on precision medicine through the creation of appropriate infrastructure, including medical research biobanks. Since disease correlations in precision medicine investigations are often weak or rare, researchers require samples in large quantities to confirm their observations. As such, precision medicine initiatives are inexorably dependent on the availability of high-quality samples through biobank infrastructures.

Research biobanks collect, process, store and distribute biospecimens (such as blood and blood derivatives, tissue samples, etc.) and associated clinical and laboratory data in a highly efficient, secure and organised manner, for research that will eventually lead to clinical applications. Prior to 2010, Russian biomedical research relied on numerous disparate collections of biospecimens driven by individual research goals and localised in separate institutions. Such collections were often poorly organised, related to the activity of a sole researcher/laboratory, and for these reasons rarely shared between researches in Russia or internationally.

Starting in 2010, however, full-scale research biobanks started to appear in Russia, either organised anew or based on the existing institutional collections of biospecimens. This coincided with the national “Pharma 2020” initiative aiming to create and support long-term the development of research-based biopharmaceutical industry in Russia. It is generally believed that national precedence belongs to the biobank of the Production Association ‘Mayak’ in the city of Ozersk,<sup>1</sup> in central Russia. Among other achievements, the work of this biobank helped to create global radiation safety standards. The ‘Mayak’ biobank was followed in 2012 by the biobank of the Almazov Federal Center for Heart,

Blood & Endocrinology in Saint-Petersburg.<sup>2</sup> Following on from these successes and to better address the huge size of the country, diversity of environmental and living conditions, as well as the ethnic diversity of Russia’s population, many leading clinical and research institutions have since established their own biobanks to support internal research programmes and facilitate better integration into global research initiatives.

In particular, both leading Russian universities, Moscow State University and Saint-Petersburg State University, now possess their own research biobanks developed with considerable government funding and operating in collaboration with affiliated clinical centres. Just in Moscow, numerous research biobanks were formed recently: in the Gamaleya Scientific Research Institute of Epidemiology and Microbiology; in the National Research Center for Preventive Medicine; in the Sechenov First Moscow State Medical University; in the National Medical Research Center for Endocrinology; the Biobank of Indigenous Population of Northern Eurasia and others. In addition to Moscow and Saint-Petersburg, biobanking infrastructures are being formed in Central and Southern regions, as well as in the Far East of Russia, reflecting the growth of precision medicine focused and other research programmes. By 2019, over 25 research biobanks operate in Russia, most of them deeply involved in precision medicine studies.

Similar to other countries, Russian research biobanks fall into the following types: i) Population cohorts, such as the biobanks of the Gamaleya Scientific Research Institute of Epidemiology and Microbiology and the Biobank of Indigenous Population of Northern Eurasia; ii) Collections focused on particular diseases, such as the biobanks of the National Research Center for Preventive Medicine and the National Medical Research Center for Endocrinology; or iii) Focusing on biodiver-



sity and environmental protection, such as the 'Noah's Ark' biorepository in Moscow State University.

All academic research biobanks are fully funded by the Russian Government directly or through local government grants, reflecting its commitment to stimulate both fundamental biomedical research and R&D programmes aiming at developing effective diagnostic tools and medicines for socially significant diseases. Importantly, Russian economic development agencies and initiatives are also playing a role in supporting precision medicine research by considering biobanking as an essential component of the overall research ecosystem necessary for the growth of innovative biopharmaceutical industries. In particular, a step-change happened when the Russian Venture Company (RVC) and Skolkovo Foundation created and supported an entirely new infrastructure model in the first commercial research biobank in Russia, National BioService (NBS); establishing a growing clinical and laboratory network and providing its services both nationally and internationally. As evidence of the importance of biobanking within the Russian National Technological Initiative (NTI), the creation of a biobanking network in five key regions of Russia was defined as a priority project in the roadmap for the HealthNet area of NTI, which covers personalised medicine and healthcare, and the National BioService team was selected for this task.

The support of precision medicine research by the Russian Federation continues to grow, often mentioned specifically by the Russian Minister of Healthcare and with more such initiatives expected to be announced. To this end, Russian biobanks form part of the essential infrastructure and in an effort to respond to the ever-increasing demand for high-quality research samples, individual biobanks now integrate into networks. Very recently, the Russian National Association of Biobanks and Biobanking Specialists (NASBio) has been formed, aiming towards disseminating modern models of biobanking in Russia, promoting and implementing internationally recognised best practices, establishing professional links and facilitating integration of Russian biobanks into large-scale research projects.<sup>3</sup> Recognising the global nature of medical research and needing to conform with international standards, many Russian biobanks are now members of the International Society for Biological and Environmental Repositories (ISBER), a leading professional organisation in the biobanking field worldwide. An official Russian translation of ISBER

Best Practices (4th ed.) was published late 2018 attracting much attention in the professional field.<sup>4</sup>

It is apparent that precision medicine research and biobanking develop together and fast in the Russian Federation. Despite some uncertainties and teething problems that typically accompany every new field, they are now advancing rapidly, facilitating the progress of biomedicine on the national level and contributing to research efforts of the global scientific community. ■

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### Disclaimer

Where authors are identified as personnel of the International Agency for Research on Cancer/WHO, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the International Agency for Research on Cancer/WHO.

**Sergey V. Anisimov**

**Oleg K. Granstrem**

**Vitali Yu. Proutski**

National BioService LLC (NBS),

St.-Petersburg, Russia

Tel: +7 812 603 2609

[info@nbioservice.com](mailto:info@nbioservice.com)

[www.nbioservice.com](http://www.nbioservice.com)

**Zisis Kozlakidis**

Laboratory Services and Biobank Group

International Agency for Research on Cancer

World Health Organization

Lyon, France

Tel: +33 472 738 411

[www.iarc.fr](http://www.iarc.fr)

[www.twitter.com/iarcwho](https://twitter.com/iarcwho)

# Health research and genomic data in Finland

In this question and answer interview, Liisa Maria Voipio-Pulkki, Director General of Strategic Affairs and Chief Medical Officer at the Finnish Ministry of Social Affairs and Health, shares her thoughts on the health research landscape and genomic data in Finland

In this in-depth interview, Liisa Maria Voipio-Pulkki, Director General of Strategic Affairs and Chief Medical Officer at the Finnish Ministry of Social Affairs and Health, tells us about the health research landscape in Finland, as well as genomic data and her future priorities. We also discover the Ministry's thoughts on the direction of the European Union's (EU) next research and innovation framework, Horizon Europe, with additional comment from Antti Hautaniemi, Senior Specialist, Senior Specialist at the Management Support Unit of the Ministry of Social Affairs and Health in Finland.

This extensive interview also reveals more about Liisa Maria Voipio-Pulkki's own role and her future priorities. She also explains her thoughts on the recent Act on the Secondary Use of Health and Social Data and its purpose to make the use of the data smooth and more secure. On the subject of data, we learn about the study concerning attitudes to the use of genomic data in research and healthcare.

In April 2019, Finland had national elections and at the time of this interview during May, the new Ministers are yet to be sworn in after which the implementation plan of the new political programme will be drafted. This is perhaps, therefore, an opportune time to look back at some of the contributions featured in Open Access Government from Minister of Social Affairs and Health in Finland, Pirkko Mattila, as background material to the interview.

In her most recent piece, Pirkko Mattila, discussed [how The Economy of Wellbeing is a means of taking a holistic approach to tackle future challenges](#). In an earlier piece, the Minister [reflected on the future priorities of the healthcare sector in Finland](#). I can also recommend her article from late 2017, where she explains [how she](#)

[aims to reduce the burden of non-communicable diseases in Finland](#).

## Where do you see the health research landscape heading in the future?

I see a good future for the health research landscape in Finland, mainly because biomedical science has never had so many powerful tools to hand! Also, because the scientific community's work is much more open to public review and ethical discussion than it used to be. And we have evidence that research can make the world a better place to live in and help people to prevent and overcome health and wellbeing problems. Of course, there are also challenges and warning signs but also emerging solutions to them. I'd like to mention only two: data safety and security are of utmost importance in the era of data-intensive research and artificial intelligence (AI). In Finland, we think that people's trust can be maintained by combining a solid legal basis with up-to-date ICT solutions. We better get prepared as authorities and care providers to this data-driven world which will definitely also affect the way clinical research is designed and reported.

Second, there is increasing competition for limited research resources and we need to justify why health research still is worth funding. There are questions like how to set research priorities without killing academic curiosity and freedom, or should we invest more in neglected health challenges globally? And finally, it is a joint responsibility of the scientific community and the health systems to find sustainable ways to adopt innovations in our everyday practice. I think that it is the last point that we have not thought over enough. It is a tough question and there is no solution that would fit all, but the ability to find sustainable adoption mechanisms will be crucial to the health research field in the years to come.

### **Horizon Europe: Challenges and opportunities in the health sector**

**In this special piece of bonus content, Antti Hautaniemi, Senior Specialist at the Management Support Unit of the Ministry of Social Affairs and Health in Finland, shares her thoughts on the direction that Horizon Europe is taking and what this means for the health sector**

I am pleased to recognise that the Horizon Europe, with an estimated budget of €97.6 billion, is the biggest ever research and innovation funding programme and will allow EU to tackle the global challenges of our time and contribute to achieving the Sustainable Development Goals. It is of utmost importance that health remains as its own cluster and that it is secured sufficient investments.

As we know, the global challenges and opportunities in the health sector are not only important for the citizens but also for the sustainable economic growth of Europe. As the Strategic Programme for the Horizon Europe is taking form, we need to look forward and place Europe in the frontline of health research and ensure that the activities under Health Cluster enable ambition and motivation in the research community. We need solid funding for basic biomedical research, translational research as well as R&I investments in public health and health systems research.

The data-driven health research is one of the cross-cutting issues in the Programme. European-level health data utilisation for research and innovation purposes is still in its infancy. The European action plan aims, for example, to support data sharing, secure access and cross-border exchange of health datasets, pilot actions and data pooling across the EU. Large-scale, cross-border and multisectoral research combining comprehensive and validated health data including register data, personal health records, biobank and genome data would open vast opportunities for Europe.

Also, as we know, the European health systems face growing common challenges: an ageing population and continuous financial pressures call for innovative solutions on how to organise health care in an equitable and efficient manner. There is, therefore, an urgent need to bring innovation and research evidence, to identify more effective and sustainable ways to organise, manage, finance and deliver high- quality care to European citizens. The results of the rapidly progressing biomedical research, discoveries in etiology and therapies, personalised approaches, pharmacological products and other innovations cannot have full impact in advancing population health without also high-level research on how to implement them on a system level.

**Antti Hautaniemi**

**Senior Specialist**

Management Support Unit

Ministry of Social Affairs and Health

### **Tell us about your own role as Director General of Strategic Affairs and Chief Medical Officer at the Finnish Ministry of Social Affairs and Health and what your future priorities are**

Finland had national elections in April and right now our main task is to provide background information for the new government's programme. As soon as the ministers are sworn in, we'll concentrate on drafting the implementation plan of the new political programme. It is always a very exciting exercise! We know

that the Finnish social and healthcare system needs to be reformed in order to improve its sustainability, resilience and responsiveness. We'll see how the new regime wants the reform to be shaped but we can say that a major change towards a more centralised governance model is on the way.

Second, we are just about to start our EU council presidency and we are currently finalising the overarching themes and official meeting agendas. For example, we'll invite both chief medical, nursing, dental and

*Continued on page 49 →*



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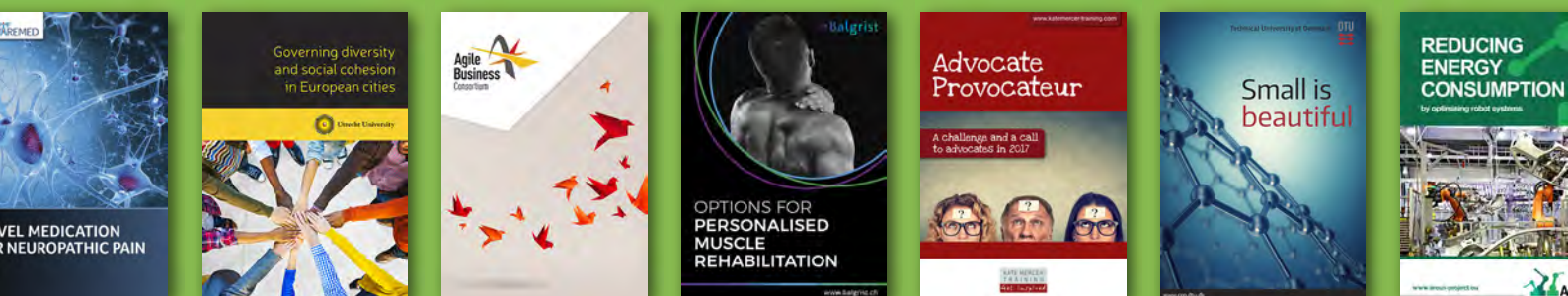
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← Continued from page 47

pharmaceutical officers to a joint meeting in Helsinki in late September. As far as we know, this is the first time when they will all come together to share experiences and learn from each other. The EU council presidency is very important to us because Finland is a small country and very dependent on trade, international institutions and the rule of law. And to be quite honest, a major part of the day-to-day work is to keep the ministry's machinery up and running! There is so much work to be done that does not hit the headlines but causes trouble if not managed on time.

### **What are your thoughts on the recent Act on the Secondary Use of Health and Social Data and its purpose to make the use of the data smooth and more secure**

The Act was discussed for one and a half years in the Parliament before it was finally passed during the last few days of their term. This illustrates how critical it was to our R&D policy and data-based health and social system governance to get the Act accepted and at the same time how tricky it was to write the legislation to be fully compatible with the GDPR. The key issue was how to ensure that all data handling is safe and secure and how to get all relevant authorities involved so that the Act would really become a changemaker. Now that we have the new legislation, we'll finally see the long-time dream of a one-stop-shop to our unique databases come true. The new data permit authority will be operational in 2020 and the service operator which will provide data handling and analysis services will follow in the next few years. In practice, this means less bureaucracy and shorter and predictable handling times for all customers. They can also provide evidence to third parties that the data they have used has been treated properly by an independent and trustworthy authority. Importantly, the new service will be made available also to foreign researchers, institutions and companies. We expect it to become a major boosted for data-intensive research, innovation, education and public policy planning.

### **On the subject of data, can you also outline your thoughts on the study concerning attitudes to the use of genomic data in research and healthcare?**

There are many studies addressing this question, with quite differing results and conclusions. I can only comment on the situation in Finland as we have



*Liisa Maria Voipio-Pulkki*

investigated people's attitudes during the preparation of our new genome law. The big picture is that people do trust the academic and health care institutions and generally support the use of genomic data in research and medical care. However, they feel significantly less secure if the data is taken outside the country to serve commercial purposes. This shows how important it is to be transparent and precise in all the information we give to study subjects and clinical patients. It is also hugely important that our healthcare professionals are well prepared to answer these kind of questions.

### **Is there anything you would like to add?**

Many thanks for arranging the opportunity to a wide set of stakeholders to meet and discuss these fascinating topics! ■

This interview was organised following the EHFG London event "Beyond the horizon - what will the world of research look like 10 years from now?" held in conjunction with REL X and hosted by the Wellcome Trust. The event was hosted by the [European Health Forum Gastein](#) in the lead up to their forthcoming event, EHFG 2019: A healthy dose of disruption? Transformative change for health and societal well-being in early October 2019, at Bad Hofgastein in Austria.

**Liisa Maria Voipio-Pulkki**  
**Director General of Strategic Affairs**  
**and Chief Medical Officer at the**

Finnish Ministry of Social Affairs and Health

Tel: +358 295 16001

[kirjaamo@stm.fi](mailto:kirjaamo@stm.fi)

<https://stm.fi/en/frontpage>

[www.twitter.com/msah\\_news](https://twitter.com/msah_news)

# Finland: A framework for genetic research

Mark Daly, Director of the Institute for Molecular Medicine Finland (FIMM), HiLIFE at the University of Helsinki, shares his expertise on medical genetic research on a population scale in Finland

Long before the completion of the Human Genome Project, the promise that genetic research would uncover critical insights about the origins of disease that could lead to new and more effective therapies has been within sight, but not within reach. Very promising examples of targeted therapeutics against specific cancers and novel lipid-lowering medications have emerged but the road from genome to disease insight to therapy has been more challenging than some had hoped.

It has become clear that many key medical insights require the integration of an enormous scale of genetic and medical information from 100,000s to 1,000,000s of humans in order to be discovered – yet in most parts of the world, the collection, aggregation and integration of such information has been precluded by many logistical and regulatory hurdles. Inherent to the problem is the challenge in striking the right balance between individual data protection and autonomy and the scientific progress that is possible only when data from many individuals is assembled and studied.

An individual's medical data is clearly one of the most private elements of personal data and must always be given the highest level of data protection and to be in the control of the individual. This is, of course, a primary goal

of the GDPR, as well as regulatory frameworks in other parts of the world. At the same time, as medical and genome sciences have advanced (and we have learned the value of their integration), providing access to these data on a large-scale to promote research discovery is seen as an opposing pressure. Indeed, critical insights relevant to both individual diagnoses and therapies in rare diseases and cancers, as well as the discovery of therapeutically actionable biology in common disease are now possible but often require genomes and health data from extremely large samples to be analysed together. How to ethically balance data protection and promote essential medical discoveries and innovation is, therefore, one of the major challenges in research medicine today.

Finland tackled this challenge proactively and efficiently with an innovative national Biobank Act in 2013. While completely protecting individual data (consistent with the later GDPR requirements), the Biobank Act facilitates responsible and approved medical research in academia or industry with several critical elements. First, is the introduction of the concept that individuals may provide a 'broad consent' for approved medical research (and, therefore, need not consent to each separate approved research project individually). Second, a straightforward

way in which previously collected samples (such as valuable epidemiological collections with extensive characterisation and longitudinal follow-up) can be transferred to the national biobank framework and used in future studies. Third, individuals consenting to join the biobank can be recontacted (based on their medical and genome data results) in the context of an approved research study, creating the opportunity to build a dynamic research resource that can be updated with not only national health registry data but individuals are invited to participate in secondary research studies. Equally important are provisions that individuals may remove consent at any time and request any data generated on their samples or data. Such a forward-looking framework has resulted in the initiation of large-scale and innovative research projects, such as FinnGen.

The FinnGen project aims to collect genome data and integrate it with national health registry information on 500,000 Finns (almost 10% of the population). FinnGen is supported by a unique public-private partnership involving the Finnish government innovation fund Business Finland and a consortium of nine pharmaceutical companies. Made possible by the progressive Biobank Act, the study has a focus on generating therapeutically relevant insights surrounding the root causes of common diseases, as well





as their progression and responses to therapy. The project will, therefore, utilise both deeply studied legacy collections, the subjects of which in many cases are quite old and newly recruited patients from hospital clinics throughout Finland (more than 150,000 individuals in less than two years).

With all individuals recruited into the Finnish biobanks, the project is then approved to perform a broad set of analyses including (from the approved study plan) the “identification of deleterious predisposing and protective disease variants, the development and genetic exploration of novel longitudinal disease progression and response phenotypes and the use of genetic information for prioritising potential drug targets”. That such analysis can be done in an ethically responsible way, with no individually identifiable data in the hands of research staff outside the approved government agencies which handle such data, is a credit to the innovative spirit in Finland and, in particular, the commitment of a population who see the benefit of an advanced medical

system comes with a responsibility to permit their data to be used in further critical medical research.

While Finland is making progress, we must distribute lessons learned and technology platforms to ensure global progress. Mechanisms for sharing personal data appropriately and anonymously across national boundaries, not just within, must be developed since human biology and medical challenges are shared by all and efforts, resources and samples in any one country are insufficient to solve the most complex medical problems. Moreover, since medical (and particularly genomic) research has been very disproportionately centred on people of European ancestry, it is ethically imperative that locally appropriate and secure genetic data sharing techniques be adopted widely in Asia and Africa, as well as Europe and North America.

Furthermore, we must accomplish this in a way that respects cultural differences and recognises the importance of capacity and infrastructure

building in under-resourced locations. Only then will we ensure maximum value is achieved from existing, as well as newly developed medical research efforts around the world. In this way, we may finally deliver on the promise of the Human Genome Project, ensuring that the fruits of medical genetics research can inform on the biology of disease in all people and lead to a new era of improved therapeutics for all.



**Mark Daly**  
**Director**

Institute for Molecular Medicine Finland (FIMM), HiLIFE, University of Helsinki  
Tel: +358 50 546 8790  
fimm-director@helsinki.fi  
www.fimm.fi  
www.twitter.com/dalygene  
www.twitter.com/FIMM\_UH

# A focus on rare disease: Paroxysmal nocturnal haemoglobinuria (PNH)

Maria Piggin, Chair of PNH Support tells us about the rare disease, paroxysmal nocturnal haemoglobinuria (PNH) and in this area, collaborations for change

**P**aroxysmal nocturnal haemoglobinuria (PNH) is a rare disease affecting between approximately one and two people in every one million and affects both men and women at different ages. PNH is an 'acquired' genetic disease, so it cannot be inherited and patients are usually diagnosed in young adulthood.

PNH is a bone marrow failure disorder where abnormal blood cells can emerge from the bone marrow lacking multiple GPI- anchored proteins as a result of a genetic defect (mutation) in the "PIGA" gene. Absence of these proteins leave the blood cells unprotected against a series of complex reactions called "complement activation" which is part of the body's normal immune response to fight infections. As a result, the red blood cells are destroyed (haemolysis) which is the main cause of PNH symptoms and complications.

PNH is often diagnosed with aplastic anaemia although patients can have one without the other. Treatment for aplastic anaemia is different from PNH and will depend on whether it is inherited or acquired.

Since June 2007, there has been a licenced treatment for PNH in Europe. This treatment blocks the complement part of the immune system. It is not curative but dramatically reduces symptoms, the most significant of which is the occurrence of blood clots (which used to be the main cause of death in patients) and allows patients to have the life expectancy of someone without PNH. It has also more recently been used safely in pregnancy, which previously had to be avoided by PNH patients due to the risk of blood clots.

Although available in approximately 40 countries, unfortunately, this treatment is not available to all PNH patients globally due to its very high cost (approximately £300,000 per person per year). Bone marrow transplants can cure PNH but are rarely used due to the risk of severe complications.

Despite the fact that PNH patients who have access to treatment are in an enviable position, the "diagnostic odyssey" which affects rare diseases generally, equally applies to PNH. GPs and haematologists need to be able to recognise a disparate set of symptoms, such as anaemia, stomach and back pain, dysphagia (difficulty swallowing), jaundice, breathlessness, erectile dysfunction, severe fatigue and dark or red coloured urine. As not all patients experience all these symptoms and especially, perhaps the most telling one, dark/red coloured urine, the recurrent stomach pain can send patients down a urology and/or gastroenterology pathway for years at a time. Anorexia has been another misdiagnosis resulting from weight loss due to difficulty swallowing as a result of the dysphagia (which results from the free haemoglobin from the damaged red cells binding and removing nitric oxide). Complications caused by PNH prior to diagnosis can lead to irreparable damage which is why diagnosis and/or referral to a PNH specialist in a timely manner, is vital.

The diagnosis process would benefit significantly from a multidisciplinary approach by the medical profession as well as timely referrals by haematologists to the PNH National Service (a specialised service commissioned directly by NHS England) based out of both St James's Teaching Hospital in Leeds and Kings College Hospital in London. These hospitals are global centres of excellence for PNH and it was thanks to Professor Peter Hillmen's research which led to the approval of the currently licenced treatment and as a result, a transformation in PNH patients' quality (and length) of life.

PNH Support is a Charitable Incorporated Organisation established in 2015 by patients for those living with PNH (and their families) in England, Wales and Northern Ireland and run by volunteers. Scotland has its own group, PNH Scotland.

One of the primary drivers for setting up PNH Support

was the need for an independent, legal platform through which PNH patients could engage with their many stakeholders including pharmaceutical companies undertaking continuing research and development into PNH, the NHS, homecare providers, the National Institute for Health and Social Care Excellence (NICE), the European Medicines Agency and other patient organisations both locally and internationally.

Of equal importance to the formation of PNH Support, was the need for a platform through which peer-to-peer support could be facilitated as it was very common for patients to never have spoken to another patient, which can be extremely isolating. PNH Support holds regional patient meetings, a biennial patient and family conference and moderates a closed Facebook group. The sharing of experiences with someone who understands, cannot be replaced.

The need to share information, common challenges, joint approaches and leverage combined numbers was a motivation in the recent creation of the PNH Global Alliance comprising PNH patient organisations from Europe, Russia and Canada. It is anticipated that this alliance will only grow to include other countries in the near future.

In the face of an impending exit from the European Union and the loss of membership by UK clinicians from [European Reference Networks](#) (ERNs), forging homegrown networks is ever more important for collaboration and knowledge sharing especially in rare diseases. For this reason, "[Together for Healthy Marrow](#)" was recently formed comprising patient organisations for the following acquired and inherited rare bone marrow failure disorders: PNH, Aplastic Anaemia, Fanconi Anaemia, Dyskeratosis Congenita and Diamond Blackfan Anaemia.

PNH Support has benefitted enormously from the knowledge and experience of European patient advocates especially those in the HIV and oncology communities. Significant challenges remain for rare disease patient advocates where independence and credibility are paramount whilst engaging with their commercial and regulatory stakeholders. Rare disease communities (with fewer numbers to begin with) have even fewer advocates with the health, time, capacity and knowledge to undertake the advocacy required to engage meaningfully with all relevant stakeholders.

The European Patients' Academy for Therapeutic Innovation ([EUPATI](#)) has done a valiant job since 2014 to train in excess of 150 patient advocates from across Europe in a variety of disease areas and is currently crowdfunding to train more. EUPATI also developed a "toolbox" of resources, case studies and guidance documents for training patients and industry about involving patients in research and development. These are all widely accessible under a creative commons licence.

"Patient involvement" in publicly funded research has been a requirement of the National Institute for Health Research's [INVOLVE](#) since 1996. Pharmaceutical companies are fairly new to the concept and value of this kind of involvement which they (and our European colleagues) refer to as "patient engagement". Leaving aside definitions, the principle of reciprocity and partnership is key. Patients, even more so in the rare disease space, are the best (and only) people to inform researchers of their 'unmet needs'. They know what research is a priority for them, what kind of trial design is going to appeal to potential participants, what study outcome measures are important to them, particularly, the relevance of Patient Reported Outcome Measures (PROMs), which are increasingly being developed for specific disease areas. PROMs identify how patients' experience a particular treatment rather than how their body reacts to it which is what is frequently measured in a clinical trial. Patients are integrally important in the research and development process from identification of the unmet need to engaging in processes with regulators and health technology assessment agencies. The collaboration and sharing of knowledge between even small patient organisations facilitate 'activated' patients to play a part in the development of more effective and patient relevant treatment options. ■

### **Maria Piggin** **Chair**

PNH Support  
[maria.piggin@pnhuk.org](mailto:maria.piggin@pnhuk.org)  
[www.pnhuk.org](http://www.pnhuk.org)  
[www.twitter.com/pnhsupport](https://www.twitter.com/pnhsupport)



# Developments in red blood cells at the Mount of Truth

The European Red Cell Society's met the partners of the EU intellectual training network RELEVANCE at Mount of Truth in Ascona, Switzerland to discuss the latest progress

Getting together with old friends and colleagues, sharing one's successes and problems, struggling for one's point of view and celebrating the spirit of discovery and admiration for the unknown over a glass of wine or a cup of coffee; all this is worth sleepless nights and disappointments of routine research work.

This is the flavour of successful conferences, such as the meetings of the European Red Cell Society (ERCS) for the partners of the EU intellectual training network RELEVANCE. Conferences of this society provide a unique platform where the academic science interacts with clinical haematology, physics and engineering science. Together, the meeting participants address the hot topics in red cell research and the needs of patients. They unravel the fundamental molecular processes behind pathologies, suggesting new treatment strategies and developing novel diagnostic technologies.

This year, the ERCS members assembled at the Mount of Truth (Monte Verita) in Ascona, Switzerland. The meeting was organised by the coordinating house of the RELEVANCE project, University of Zurich, together with the Swiss Federal Institute of Technology (ETH) Zurich.

Since 1900, Monte Verita has been home to creative souls with alternative ways of thinking from all over the

world. Starting as a utopic settlement of vegans and sun-worshippers, it then became a sanatorium and a meeting place for theosophists, reformers, anarchists, communists, social democrats, psycho-analysts, followed by literary personalities, writers, poets, artists and dancers. Finally, Monte Verita turned into a podium for researchers, such as ERCS community members.

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**“Misdiagnosis leads to choosing the wrong treatment strategy. Surgical removal of the spleen (splenectomy) helps to increase haemoglobin levels in patients with spherocytosis, but increases the risk of thrombosis in patients with xerocytosis.”**

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The main focus of the meeting was personalised diagnostics and therapies for each unique patient. For this, precise diagnosis of the cause for the disease should be identified and best possible symptomatic therapy provided in case the genetic cause cannot be treated directly. When transfusion is required, blood for transfusion should perfectly match the patient's group.

The achievements of RELEVANCE consortium partners presented in all of these areas were acknowledged by the colleagues from all over the world from the USA to New Zealand.

In her talk, Marieke von Lindern from the Sanquin Blood Bank in Amsterdam addressed multiple strategies that she

and her colleagues pursue to achieve self-renewal of human erythroid cells, which give rise to new red blood cells in a bioreactor. The group developed a protocol of “growing patient's own red blood cells” or red cells of “universal donor”. These cells, formed from immortalised “universal” stem cell lines, will lack most blood group-defining antigens and may be used to generate vast amounts of red blood cells as required for all patients. This is particularly important for blood transfusions as there is no risk of developing an immune reaction against the “foreign cell types” with “universal” stem cell lines.

Gaining knowledge on the structure and function of the red blood cell membrane is critical for the successful treatment of blood disorders caused by mutations in proteins building the cytoskeleton and ion-permeable channels. At the University of Pavia, the changes in cytoskeleton during maturation of young red blood cells, reticulocytes, to mature erythrocytes was explored by Giampaolo Minetti and his group.

According to his findings, selective sorting of proteins forming the cytoskeletal mesh and of the proteins anchoring it to the lipid bilayer requires the active participation of cholesterol rafts within the membrane. Once mature, the cytoskeleton forms a uniquely dynamic structure making red blood cells stable and

highly deformable at the same time. It controls cell shape and volume and its rigidity, thus, controlling the red cell lifespan. Damage of the cytoskeletal integrity and stability occurs with cell ageing or can be caused by mutations resulting in production of aberrant building blocks. All participants of the RELEVANCE consortium contributed to the investigation of the cytoskeletal structure and function.

Changes in cytoskeletal structure due to the mutations in the formation of proteins are the cause of multiple rare anaemias that may be recognised by the characteristic alteration in cell shape and increase in a variety of forms of red blood cells.

At the ERCS meeting, Asya Makhro from the University of Zurich presented specific algorithms which were developed to detect the mutated protein from the analysis of microscopic images of erythrocytes without the requirement for an expensive genetic test.

According to the presentation of Greta Simionato from the University of Saarland, images of diseased red blood cells may be used to assess severity sickle cell disease and for analysis of treatment success. Image analysis software for such tests is developed by the early stage researcher Ario Sadafi from Arivis AG and at the University of Saarland.

Due to a high degree of heterogeneity, it is essential to analyse stability of single red blood cells of patients with hereditary anaemias. Such an approach gives more information about the cause of disease, its severity and responsiveness of each individual patient to therapy.

At the meeting, Niamh Kilcawley from Epigem and Leonid Livshits from the

University of Zurich presented the first results of a new device, the MeCheM analyser, testing membrane stability of individual red blood cells in flow in the clinical settings.

MeCheM analyser was used at the Emek Medical Centre in Afula, Israel, in monitoring a new therapy for sickle cell disease and for the screening of blood samples of patients with various other forms of rare anaemias.

**“Gaining knowledge on the structure and function of the red blood cell membrane is critical for the successful treatment of blood disorders caused by mutations in proteins building the cytoskeleton and ion-permeable channels.”**

Discovery of a mutation in ion channel PIEZO1 transporting calcium ions into red blood cells as a cause of xerocytosis a decade ago gave rise to a new class of rare anaemias, channelopathies. These diseases are difficult to diagnose and distinguish from hereditary spherocytosis, which is caused by mutations in structural elements of the cytoskeleton.

Misdiagnosis leads to choosing the wrong treatment strategy. Surgical removal of the spleen (splenectomy) helps to increase haemoglobin levels in patients with spherocytosis, but increases the risk of thrombosis in patients with xerocytosis.

The urgent need for new, simple and reliable diagnostic devices was addressed by a group of RELEVANCE partners (Nanion, Biological Station Roscoff, University Medical Centre Utrecht, Universities of Saarland and Zurich and Epigem). Together, they developed a battery of tests for identification of xerocytosis and Gardos channelopathy. The tests include gene

array, detection of the abnormal function of ion channels in individual red blood cells using automated and classical electrophysiological methods, the resistance of diseased red blood cells to swelling and image analysis approach. Used alone or in combination, these tests will allow precise diagnosis and monitoring of the efficacy of therapy for this group of patients. A number of meeting participants pointed out the sound contribution of the RELEVANCE consortium to the overall success of the 22nd ERCS meeting at the Mount of Truth.

One of the keynote speakers and a member of the jury for the young investigator awards, James Palis from Rochester University, shared his impression of the meeting with these words: “I loved the enthusiasm of the young folks at the posters, which tells me that the meeting was a success and that future of the field in Europe is in good hands!”



**Anna Bogdanova**  
**Professor and Head of Red Blood**  
**Cell Research Group**  
 University of Zurich – Relevance project  
 Tel: +41 (0)44 635 8811  
[annab@access.uzh.ch](mailto:annab@access.uzh.ch)  
[www.relevance.arivis.com/](http://www.relevance.arivis.com/)

# Universal Credit and mental health: “It was a confusion”

Carolyn Lochhead manages public affairs and communications at mental health charity SAMH (Scottish Association for Mental Health). In this article, she reveals the findings of a report that underlines the charity's report concerning Universal Credit and the impact it has on mental health

SAMH's new report "It Was A Confusion" finds that Universal Credit is not working for people with mental health problems. SAMH believes that no one should be transferred to Universal Credit until the issues it identifies have been addressed.

SAMH has made a set of recommendations to the UK Government, including rethinking the assessments process, better guidance for Work Coaches and scrapping Digital by Default.

The introduction and roll out of Universal Credit is the most significant change to the UK social security system in the last 20 years. As Scotland's largest mental health charity we have been increasingly concerned about the impact this change has had on people with mental health problems.

**“The Universal Credit system relies on work coach discretion when setting job searching and work-related conditions. The onus is on the person in receipt of Universal Credit to disclose their mental health problems which can be very challenging, particularly as work coaches are not specialists in mental health.”**

To better understand the effect of Universal Credit on people with mental health problems and make recommendations to UK policymakers, we published the report: "It Was A Confusion": Universal Credit and Mental Health: Recommendations for Change. To inform the report we analysed the latest literature on Universal Credit, held a seminar with sector colleagues and interviewed three people with experience of Universal Credit.

## So what did we find?

Far from simplifying the UK's social security system –

an aim SAMH supports – the introduction of Universal Credit has added to the complexities faced by people with mental health problems. This is causing hardship and emotional distress to people attempting to engage with the system. We found problems across the Universal Credit journey, from applying for the benefit to being assessed, the conditionality regime and managing a claim. Below are some of our main findings.

### Applying for Universal Credit and Digital by Default

People applying for Universal Credit are expected to apply and manage their claim online. We found only limited safeguards allowing people to make alternative claims by phone. This digital by default approach results in significant problems for people without digital literacy or access to the internet and IT equipment. Findings from the Department of Work and Pensions (DWP) itself found that 24% of people with long term conditions (including mental health conditions) could not register for Universal Credit online; with 53% needing support to set up a claim.

### Assessments for disability components

Where someone has a disability they may be eligible to receive the limited capability for work and work-related activity components of Universal Credit. We found that assessment for these components, mainly through a face to face Work Capability Assessment (WCA), does not work for people with mental health problems. Assessors can lack expertise in mental health, sometimes resulting in stressful stigmatising behaviour causing distress to people being assessed.

People waiting for assessment can still be forced to comply with work-related activities, such as job searching, even when they are unwell. This is different from



the legacy Employment Support Allowance (ESA) system where conditionality is not applied until after someone has the results of their WCA.

### Managing a Universal Credit claim

The case studies and literature highlight difficulties for people with mental health problems successfully managing their claims, resulting in the risk of receiving a benefit sanction. Issues included the built-in five-week wait for a first Universal Credit payment, resulting in rent arrears; inconsistent payments for people with varying incomes; and complying with the conditionality regime.

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**“SAMH has made a set of recommendations to the UK Government, including rethinking the assessments process, better guidance for Work Coaches and scrapping Digital by Default.”**

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The Universal Credit system relies on work coach discretion when setting job searching and work-related conditions. The onus is on the person in receipt of Universal Credit to disclose their mental health problems which can be very challenging, particularly as work coaches are not specialists in mental health.

### What is SAMH recommending?

The report makes 18 recommendations to the UK Government and jobcentres to improve the Universal Credit system for people with mental health problems. These recommendations cover the full Universal Credit journey from application to managing a claim.

Fundamentally, we are calling on the UK Government to not transfer anyone onto Universal Credit from the legacy benefit system until flaws with the system are fixed.

The recommendations include:

- Scrapping Digital by Default;
- Ensuring no one has to undertake work-related activities while waiting for a WCA and its outcome;
- Abolition of the unjustified five-week waiting period for first payment;
- Introducing a non-repayable assessment grant for new Universal Credit claimants, to replace advanced payments;



Carolyn Lochhead

- Jobcentres to proactively gather information about the person's health, prior to setting their Claimant Commitment;
- Strengthened DWP guidance to Work Coaches over setting appropriate conditions for vulnerable claimants, including people with mental health problems and;
- Scrapping benefit sanctions for people with mental health problems.

We believe that these changes, with the other recommendations in the report, will radically improve how Universal Credit works for people with mental health problems. Far from simplifying the social security system and supporting people with mental health problems, the current regime is actively causing distress and financial insecurity. This has to change. ■

### Carolyn Lochhead

#### Interim Head of Communications and Public Affairs

Scottish Association for Mental Health (SAMH)

Tel: +44 (0)141 530 1000

[communications@samh.org.uk](mailto:communications@samh.org.uk)

[www.samh.org.uk](http://www.samh.org.uk)

[www.twitter.com/samhtweets](https://www.twitter.com/samhtweets)

# Mindfulness, mental health, wellbeing and poverty

Karma Jiga, CEO of the Nilupul Foundation introduces adapted Mindfulness-Based Interventions (MBI) that reveals positive changes in health and wellbeing for the socioeconomic deprived (SED)

**S**tress, now the subject of major research, is something most of us in western society are familiar with. When prolonged, it has been linked to a myriad of physical and mental illnesses and disease and has proven to be particularly toxic for the psychological health of the poor. Not surprising then, that mental health issues seriously affect 1 in 3 people. To cope, we are presently offered two solutions, pharmaceuticals or psychological-based approaches. The first is costly and can have unwanted side effects, while the second, though medication-free, can have high initial costs but offers fewer side effects. This begs the question, could the potential benefits of the newer psychological approaches, such as Mindfulness-Based Interventions (MBI) prove to be significant?

## MBI genesis and development

Jon Kabat Zinn's original Mindfulness-Based psychological approach, Mindfulness-Based Stress Reduction (MBSR) derives from his wish to help those who had "fallen through the cracks" of modern healthcare. He melded modern scientific rigour and Eastern Mindfulness practices and brought non-religious mindfulness into the mainstream of medicine and society. This ushered in the development of a new generation of psychotherapeutic interventions, such as Mindfulness-Based Cognitive Therapy (MBCT). As part of this wave, Karma



Jiga, a practitioner highly trained in Eastern and Western-Based Mindfulness, combined and adapted MBSR/MBCT techniques to develop an MBI (Headroom) suited to the needs of socioeconomic deprived (SED) populations (Jiga, Kaunhoven, & Dorjee, 2019).

## The Headroom MBI

Headroom is typical of most MBIs. It consists of a nine-week group mindfulness programme and a science-based psychoeducational component related to stress and wellbeing. Mindfulness may be characterised as the awareness and acceptance of what arises in and around you, as it happens. Acceptance is acquired through gradually learning to allow thoughts, feeling and emotions to come and go without judgement while sitting, standing, lying down, walking and talking, the very stuff of life itself! Thus, MBIs enable participants to see the programme's relevance to life and

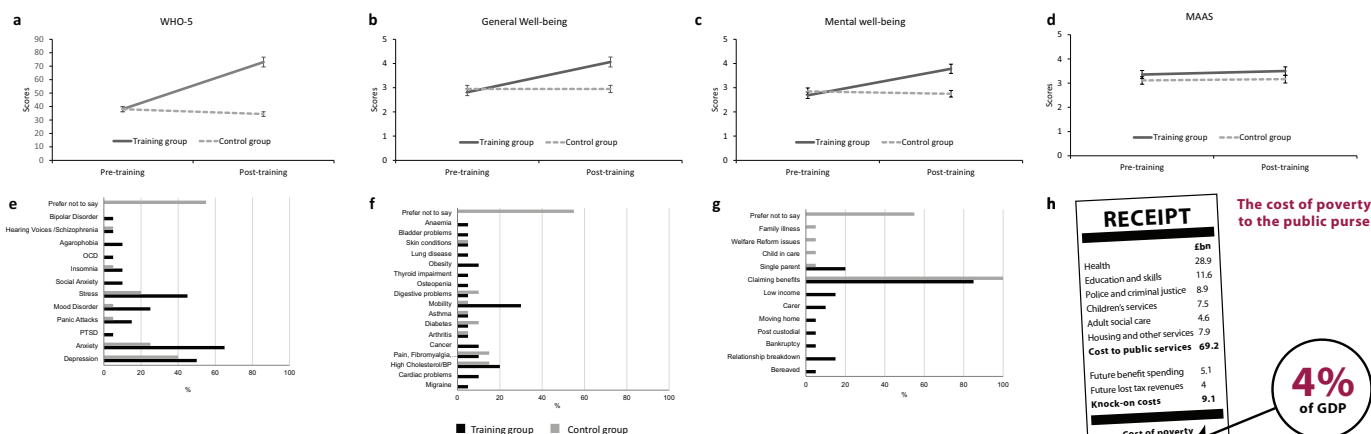
living, and dispels the myth that meditation has no relevance to them or their way of life.

## Research & efficacy

Empirical verification of a programme's efficacy is important in any field nowadays. Fortunately, MBI research has, in the main, shown positive effects in a variety of populations ranging from moderate to significant. The effects of MBIs within SED communities, however, is a fledgling area of study (a dozen or so studies). Karma Jiga's Headroom research programme presents a unique, mixed method study from SED communities which, according to Mindfulness Journal's editorial team, "will make an important contribution to the literature".

## Outcomes

Only 40 (20 test, 20 control) out of 107 applicants, adults (over 18) from SED communities completed Headroom. Their general and mental wellbeing



a The WHO-5, b General Well-being, c Mental Well-being, d MAAS, e mental health information, f physical health information, g socioeconomic factors and h The cost of poverty to the public purse

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were assessed before and after through a combination of widely-used and verified 5-point Likert self-report measures, (e.g.WHO-5<sup>a</sup> & MAAS<sup>d</sup> \*), a unique pre- and post-course thematic analysis and two additional open-ended questions<sup>b,c</sup>, which allowed participants to express themselves. This distinctive mixed method study demonstrated significant reductions in stress, anxiety and depression. It also indicated an increase in awareness and wellbeing and better coping and long-term management of the toxic stress of living with chronic low income. This, despite the complicated cocktail of circumstances<sup>d,e</sup>, mental health issues<sup>f</sup>, genetic inheritance and the ineffective MAAS, which showed no significant change between groups.

## National benefits – cost effectiveness

According to the Cabinet Office, entrenched poverty results in 2½% of every generation suffering a lifetime of disadvantage, harm and genetic change, which, according to some affects brain development and long-term health over several generations. This, according to the Rowntree Foundation, costs the nation and public services dearly<sup>h</sup>. However, the UK Government commissioned reports affirm that MBIs, if part of a government wellbeing strategy, would make

the poor easier to reach and save the nation money. It could reduce the burden on healthcare, social, family, education and mental health services. The NHS adoption of MBCT is perhaps an indicator of MBI potential.

## The Headroom Project

Headroom demonstrates that community-based MBIs are not only feasible, acceptable, cost-effective and aid social cohesion, but, that they could be a useful and beneficial part of national and local government wellbeing policies. A grant-funded project, Headroom is delivered for free to those earning less than the real living wage in SED communities in Dundee, Scotland, where interest and participation are increasing as the word of its benefits spread. Headroom graduate successes include a community advocate for Dundee Health and Social Care Partnership through Advocating Together, as a voice for learning disability and autism in the city, and another, employed through SAMH (Scottish Association for Mental Health) by Chrysalis Tayside NHS to support mental health recovery and employability skills through therapeutic horticulture activities. To continue to build on such successes and expand the project city-wide, transfer the programme from city to city, and expand the research to better under-

stand the mechanisms that bring about such positive change, funding is needed. Any help or suggestions would be greatly appreciated.

## Conclusion

Ironically, while David Cameron was touting the need for a General Wellbeing Index alongside GDP, and his government were implementing draconian austerity measures that according to the UN, breached human rights and increased poverty in the UK, these same MPs were accessing MBIs in parliament! Surely, as they say in the UK, 'what's good for the goose, is good for the gander'!

\*World Health Organisation's Well-being Measure \*Mindfulness Attention Awareness Scale.



**Karma Jiga**  
**CEO**

Nilupul Foundation  
Tel: +44 (0)1382 872 020  
karmajiga@nilupul.org  
www.nilupul.org



# Emotional fitness for university students

Nick Bennett, CEO at Fika, puts forward the case for a positive and preventative approach to mental health for university students, drawing on learnings from physical fitness and positive psychology

The past four decades have taught us huge amounts about the importance of regular physical exercise – from how to build workouts into our routine, to the many health benefits of proactive physical fitness.

When it comes to our mental health, however, recent decades tell a very different story. The university population has been one of the worst hit by the lack of prevention in mental health.

In March 2019, the UK's largest ever mental health poll of university students revealed 'alarmingly high' levels of distress and illness among students.

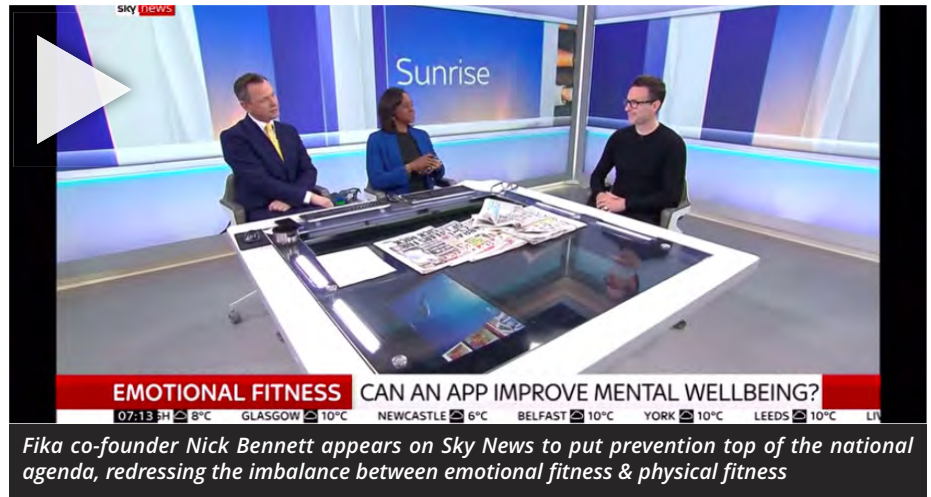
According to industry insiders, a huge amount of resource is being spent on the treatment end of mental health in higher education – but there is very little investment on the preventative end.

As stated in November 2018 by (then) Health & Social Care Secretary Matt Hancock, "prevention is better than cure".

The case for a preventative approach to emotional wellbeing in UK universities has never been more pressing. Health tech company Fika is set to lead this charge.

## Fika is bringing emotional fitness to UK students

Fika is a new, science-backed organi-



sation on a mission to mainstream emotional fitness across the UK's universities. Offering 5-minute emotional workouts on the Fika app – Fika wants to raise awareness that emotional workouts are as important as gym sessions for university students.

The Fika app launched earlier this year, rolling out closed trial partnerships with the Universities of Coventry, Exeter, Lincoln and Manchester Metropolitan – offering a scalable, preventative approach to student wellbeing.

Professor Tim Quine, Deputy Vice-Chancellor (Education), University of Exeter said: "We are excited to be collaborating with Fika and the other universities involved at this early stage in the journey to emotional fitness, and look forward to seeing the programme develop."

Rebecca Schaaf, Pro Vice-Chancellor at Bath Spa University, said: "We are very supportive of Fika's innovative approach, focusing on prevention rather than cure – and are excited to see how it will contribute to the broader range of services we provide to support student wellbeing at Bath Spa."

## Learning about emotional fitness from athletes

Said Dr Frances Longstaff, Head of Psychology at Fika: "We have a lot to learn from athletes when it comes to our emotional health. Athletes understand that mindset is essential, and they receive specialist training to hone not just their physical performance, but their mental performance too. The Fika app draws on these learnings to help students optimise their mindset, enabling them to reach peak performance in their studies and relationships."

## Students care about emotional fitness

In Fika controlled diary studies and research focus groups, students have reported benefits including improved self-reflection and self-awareness, evolved active listening skills and deeper friendships.

“Emotional fitness is about being emotionally healthy, having awareness and being able to handle a variety of emotions, both good and difficult ones.”

“Emotional fitness is about increasing your resilience, being stress-free and having work-life balance.”

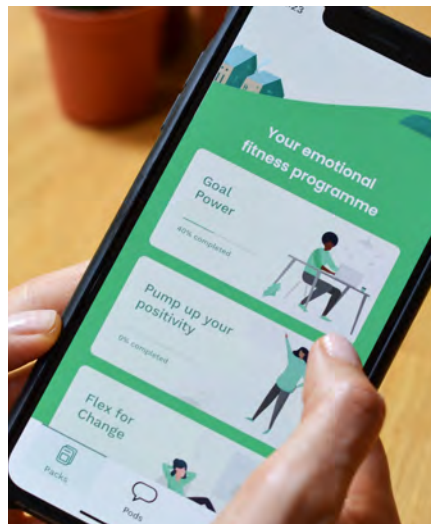
“Emotional fitness is about calm, being happy and relaxed. Being able to express your emotions and not ignore them.”

Fika’s peer-to-peer model signals benefits for social cohesion across its partner universities, as well as the academic performance both of individual students and the university as a whole.

Said Sharon Rankin, Wellbeing Services Manager at London Business School: “Fika is the first initiative that has really raised my hopes that the sector can take a new direction. The app promises to actively promote inclusion across the university as a whole, as well as destigmatising and normalising emotional wellbeing. It is a really exciting concept for higher education.”

## An evidence-based approach

Fika is backed by decades’ worth of science: the app is underpinned by theory and research from across sports psychology and positive psychology as well as cognitive behavioural therapy (CBT), acceptance



commitment therapy (ACT) and solution-focused therapy.

Seven psychologists have been involved in the two-year process of Fika’s development.

Critically, though, Fika is also undertaking its own programme of academic research: Aiming to build the UK’s largest body of empirical evidence proving the benefits of regular emotional exercise.

Furthermore, with UK universities losing millions each year through student attrition, Fika has the potential to save universities millions by boosting student retention.

Said Dr Roger Bretherton, Principal Lecturer (Enterprise) at the University of Lincoln: “As an academic psychologist, Fika is the approach to mental health I’ve been waiting for. Emotional fitness places the ability to care for ourselves and one another back in our own hands.”

Jennifer Moorby, Head of Student & Graduate Employment at Manchester Metropolitan University, said: “University life does not end with graduation. We know that wellbeing plays an important part in personal success

and commend the science-backed Fika mission with our support.”

## Raising the national agenda of the importance of emotional fitness

In the long-term, Fika aims to become a cultural phenomenon across universities worldwide: Safeguarding the wellbeing, careers and personal lives of the next generation.

Fika is in the process of lining up two public think tanks on the future of student emotional fitness – gathering views from university vice chancellors, higher education policy advisors and sector analysts.

Said Fika co-founder and CEO Nick Bennett: “Our think tanks represent an opportunity for our university partners and visionary leaders to come together and rewrite the future for the wellbeing, careers and relationships of the next generation of talent. The emotional fitness movement will be at the centre of that future – and we’re calling on all universities to get in touch and be part of this movement.”



**Nick Bennett**  
Co-Founder & CEO  
Fika  
Tel: +44 (0)790 027 3797  
Nick@Fika.Community  
www.fika.community  
www.twitter.com/TheFikaApp

# What is the future of online mental health treatment?

Henry Jones spoke to Nishat Choudhury from Open Access Government about mental health platform Big White Wall (BWW), in light of the oncoming UK Government White Paper on Online Harms

**H**enry Jones is the CEO of BWW, a social impact enterprise which is fighting to address the necessity of online platforms, to help people with their mental health problems.

Whilst generally, young people are aware of the available help via the NHS, they are also wary. The formality of the process, the lengthy waiting time, and the imagined lack of control over what happens next are combined with a hefty dose of stigma about being mentally ill. Whilst this stigma is steadily being dissected, there is still a lot of work ahead of healthcare providers.

When an individual's mental health is bad and they accept the need for help, they may have to wait for a long time before seeing a therapist. If they doubt themselves until intensifying symptoms become unignorable, that wait becomes excruciating, often hopeless. If they have a secret their parents can't know, they may never risk attaining help.

These limitations keep people from seeking real help. Where do we really go for comfort when we are hurting?

The internet.

Friends through instant messaging or Skype. Online forums where anonymity helps open discussion. Questions typed into Google when human interaction feels too draining. Technology and young people are often regarded with fear. Instagram regularly comes under fire for influencing vulnerable minds, e.g. the platform is infamous for idealising a barrage of photoshopped bodies, causing eating disorders and a rise in cosmetic surgery.

But the internet is going nowhere.

Big White Wall has an approach to mental health and technology that explores mental health prevention via immediate therapy. Below, their CEO Henry Jones discusses some of their ideas with me.

**Nishat: Thanks for taking the time to talk to us today, we're very interested in the things you're doing. Firstly, I want to ask you what BWW is doing in the realm of mental health?**

"We provide two fundamental offerings, and some overlapping services in the middle. One of our core offerings is a peer-to-peer, anonymous 24 hours a day presence monitored by professionals. It is a platform for people to share and support each other in the community, around mental depression and anxiety.

"So that's the prime offering.

"They get the opportunity to go onto a community and go on to talk and engage with other people in a very safe environment. And help each other really, with the added support of our wall guys. They are professionals put there to make sure that it is safe and secure and nothing inappropriate happens."

**Nishat: That's interesting. Because talking about the digital landscape right now, I know you focus on the dangers of online content, so what do you think your greatest fears are for mental health in this climate?**

"Look, I am a strong believer in technology being used for good or for bad. And I think there's a lot of press around technology being used for bad. There is a



problem, it is building. I heard someone talk about it the other day, the way we've been talking about sugar and the problems it causes around obesity has really had a huge impact on our culture, our people and our society. And I think that online, unless done properly and managed and safely done, could absolutely be the next issue.

"It exposes our youth to a whole lot of issues, that needs to be controlled and managed. So, my biggest fear is that, having been in the technology space for the last 20 odd years, that impact is has becomes all-negative, and not good.

"So I think one of the key things is to talk about the challenges technology provides, the opportunity on the other side is that it has the amazing ability to reach and give access to a lot of people.

"So that's where technology can play an amazingly positive impact in creating reach and access if done correctly. It isn't the technology that's the problem, it's the way it is used, the way it is guarded, the way it's regulated. I think my biggest thought is, we lose control of this, and it creates a lot of damage, which we don't start addressing early enough."

**Nishat: In terms of regulating it, what do you think should be the first step? You said your greatest fear was losing control, so how do we keep control? Do we intervene earlier, do we make people aware of what can happen?**

"I think there's a path for many different things.

"I think there's a role for education, you know how we educate our young people around the impact of social media, the good and the bad, how they manage that themselves. I do think there is a role for regulation, you know how do we make sure really inappropriate materials are not provided to children?

"You know I have young children, and it terrifies me what they may come across. I think there probably is, either for the industry to self-regulate or for the government to regulate.

"Actually most of the population, when they have a question or query, about anything these days they typically go online to get an answer."

**Nishat: Straight to google.**

"Yeah, straight to google, or straight to a community, or whatever. One of the things we talk about in the paper is we're not going to change that behaviour. And it is crazy to think that we are.

"So, what you want to do, is to provide environments that when people go online, they know, if I've got a mental health issue, I want to go onto a community that is built to cope with that. Instead of trying to say this is all about regulation it's also about giving people options.

"One of my visions for BWW or a service like that, is that by the time my eldest son gets to 16 I can say to him, look if you go online and if you're suffering from depression or anxiety, go online, but go here. It is not the responsibility of the likes of Facebook and Instagram, to ultimately be the answer to depression and anxiety.

"They've got to make sure it's safe and secure and all of those reasons but that's not what they've been set up for. I think that's partly education, partly regulation."

**Nishat: So you've noticed these platforms aren't equipped to do these things, and you're filling in a gap that needs to be filled?**

"Yeah, that's not what they've been built for. It's not their business model and it's not what their drive is. I think that we should be using technology to create things that are specifically set up to deal with this. And are in and run and managed in a model, in a way that youth will want to use.

"It's about encouraging people to know that you don't go to your grocery shop if you're feeling ill you go to your doctor. You know it is the same online."

**Nishat: And how old is your son so we have a timeline on these ambitions?**

"Thirteen. Three years."

**Nishat: Moving on from the concept of being online, I wanted to discuss the NHS long term plan. The specific number that the Government promised by 2023 is £2.3 billion a year. Is that enough?**

"I'd love to be able to tell you it's enough. But what I will say is I think it's great that they are putting serious allocation to it. I think the challenge with the NHS plan is that probably underestimates how big this problem is going to be. Their predictions I think will be wrong in terms of how many people need help.

"I also think they are looking at very traditional methods that provide a bit of technology. But I think they've got to rethink the model. I think the biggest problem is the scale of the issue and trying to solve it the same way as before with a little bit of technology is not going to do it. They also don't address the issue of things like, stigma. A lot of people who come to the BWW have never shared their problem with anybody else.

"And a lot of the reasons behind that are stigma, maybe it's a youth thinking about their sexuality, maybe it's a religious issue or maybe they can't share it with someone. I don't think there is enough understanding about how youth need to interact with mental well-being.

"There's not enough of that 'how do youth want to interact with us?', it's more like, 'how do we want to interact with youth?' What they should be saying is let's create an environment the youth want to interact with as opposed to one we want them to interact with."

**Nishat: So is Big White Wall that environment for youth interaction with mental health treatment?**

"It is an environment. At the moment, we have 50 universities on it, we have access to over half a million university students have access to the platform. I think it is an amazingly powerful thing, the impact it's having on people's lives – when you get quotes saying, because of this I was able to come off my drugs or this is the first time I've ever really opened up to someone.

"We talk about how your next therapist could be the person sitting next to you on the bus. That help is coming from other people who are experiencing the same thing. And is not a cost to the National Health Service, it is people helping people. It goes back to the very basis of the value of community.

"We always liken it to the story of, you arrive at university and we see a peak in activity from our university

students over fresher's week. This is not surprising. You've got students arriving at university, their first time away from home maybe. They're looking at Facebook, and on Facebook everyone is saying oh look what a wonderful time, I've been at this party and I've been at this party.

"And they're sitting there thinking god my life is awful.

"You know, the ability to go on something like the big white wall and say, I'm feeling awful. Then a load of people to come back and say don't worry. Same thing happened to me, this is what I did about it, you're not alone.

"But you can imagine that student, if they can get early intervention, and go oh I'm okay. I'll go back to my life, I'm not the only one."

**Nishat: It doesn't escalate.**

"Yeah, or they sit there, and in 13 weeks they go to their doctor who then tells them you've got to wait another 13 weeks. And you see two very different paths happening. You asked about the NHS white paper. I think there is not enough around really catching people early."

**Nishat: You said earlier there's a lot of stigma around mental health. It sounds to me like BWW is so far removed from the NHS, and doctors, and waiting rooms. So would you say people can access it without having that same sense of guilt or shame?**

"And they're anonymous. They are in a very safe world talking to people like them who are suffering through the same thing. But no-one knows who they are so they can talk openly and frankly. There's no risk that it will get back to their employer, their university, their parents, if they don't want it to."

**Nishat: So, moving on a little bit from that, mental healthcare policies in this day and age. Do you think our government as it stands is doing enough? We've spoken about what the NHS has planned, but do you think there's enough awareness being raised by the government as a whole? Are we moving towards the digitalisation that you are describing?**

"Talking about governments, I don't think anywhere is doing a great job on this. And I think it is because it is becoming such a problem. So, you know, we work in Canada and I think everywhere you see this becoming more and more of an issue. So, I think the government are good in that they've identified it as a critical issue, I think that they need to throw the net wider.

"I think they either do that now or it will become such a big problem it will be forced on whoever is in government. But this isn't just the government, it's the medical community, employers, everyone needs to say hang on, I think we've got a big problem coming.

"I'm just not convinced people are being bold enough in their thinking.

"I don't know if it's government, but technology is part of the solution, alongside education, regulation. But I think people are trying to do it, and it's not an easy thing to do. I could sit here and say oh I could do it so much better but it's an immense challenge. It's going to need a lot of thought, some brave choices. I don't want to be too critical of the government, I don't think anyone has particularly got a handle on it at the moment."

**Nishat: Yeah, being online, having mental illnesses: these things are new in how they're being combined. In relation to that, can you think of anyone else working to fight the issue of mental health treatment access?**

"I think there is a couple of organisations that we're talking to, that is focused on youth and then there's another organisation focused on medicine, that are really thinking about the care pathway. And really starting to think about how you can leverage, community technology and faith and secure environments.

"So, if you get people helping each other, it's a really scalable solution that's cost effective but can help you reach ten times more people. You think about the BWW if you have a six-hour period. In that six hours you could have 5000 people on the community but only one professional overseeing that group. So that's highly scalable. The ones who are really thinking about how to get that scalable solution and get a lot of people early, will not take a huge amount of capacity but also

save the capacity that's needed in the NHS system upstream. So, there'll be less people who need therapy and treatment.

"I think those organisations are making the right decisions. They're thinking about scale and technology. My hat goes off to them. You talk about metrics and things like that, I think we've got to figure out a way to measure the impact of early intervention."

**Nishat: Because you have a focus on anxiety and depression, do you think that your services can be extracted for other mental illnesses?**

"Yeah, I mean we talk about anxiety and depression, but you know we're just giving out therapy for long term conditions. It may be caused by an illness, a student going to university, an addiction or whatever. Anxiety and depression come for many different reasons and we're there to support that. I'm sure that the power of community and safety and anonymity can help in many ways.

"If people are worried about an addiction problem, maybe there's ways it could absolutely be used for them. We're a social impact business. Our backers back us because they want to support something that does good but doesn't rely on charity. Our core mandate is to access as many people as possible in a sustainable way.

"My goal is as I said, to make sure as many people as possible have access to this platform so they can make their lives better. We basically believe we have enough to deal with in anxiety and depression, so that's where we're going to Major. All the signs are saying this is growing and growing: we want to be part of the solution that helps lessen the impact of it on peoples lives, employers the community and the cost to the NHS."

"It's been really good to talk about it." ■

**Henry Jones**  
**CEO**

Big White Wall (BWW)

Tel: +44 (0)203 405 6196

theteam@bigwhitewall.com

www.bigwhitewall.co.uk

www.twitter.com/BigWhiteWall1





**Paul Bomke**  
CEO  
[Paul.bomke@pfalzlinikum.de](mailto:Paul.bomke@pfalzlinikum.de)

**Lena Kuntz**  
Project Officer  
[Lena.kuntz@pfalzlinikum.de](mailto:Lena.kuntz@pfalzlinikum.de)

# Because they know how it is

## Peer counselling at the eye level in the Palatinate region

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The Federal Participation Act of 23rd December 2016 changed on 1st January 2017 concerning the performance right of the social code IX and described with its changes, a fundamental paradigm shift in the right to rehabilitation and participation of people with disabilities. On this basis, the Federal Ministry of Labor and Social Affairs (BMAS) promotes the establishment of supplementary and complementary independent participation counselling centres in Germany as of January 2018. Subsidies from federal funds are initially granted for a total of three years.

The Supplementary Independent Participation Advisory Service (EUTB) is a counselling centre for people with disabilities or for those at risk of all kinds of disabilities. But it also serves relatives of such people and as such, the EUTB offers a trustworthy point of contact. In addition to other established counselling services offered, the EUTB is independent of other service providers and aims to help those seeking advice. The free consultation always takes place on an individual basis and is geared towards the needs and possibilities of the person seeking advice. The focus of the EUTB is on peer counselling, which means that the counsellors themselves are impaired and can, therefore, treat their clients at an even-handed level. Users with experience advise users. The peer consultants are qualified as part-time counsellors and accompany advice seekers through the jungle of the benefits system.

In the southern Palatinate region, the EUTB was set up in the city of Landau in the south of the Palatinate region as a cooperation project between GPZ Vorderpfalz and the state network, Netz-G RLP. The GPZ Vorderpfalz (a subsidiary of the Pfalzkrlinikum) is, together with the state network self-help mental health RLP e.V. (NetzG-RLP), a provider for EUTB Landau. The network NetzG-RLP is an association of people with mental health/illness experience and acts nationwide as experts in the field, which arises from their own concern.

The “participation-advisers” of EUTB Landau are themselves severely disabled and can, therefore, act as peers with both their professional and relevant knowledge. It is precisely this aspect of peer counselling that can facilitate an eye-to-eye exchange and a sense of understanding and acceptance. Due to their own disability-related experiences, the advisors of the EUTB Landau are sympathetic when it comes to understanding the situations of those seeking advice. In doing so, they acquaint themselves to the needs of the respective person to reduce any participation barriers.

In addition, the psychosocial situation is taken into account during the counselling so that joint solutions can be developed, accounting for the skills of the individual seeking advice. The clients are supported in finding a way to participate for themselves and without being influenced by their own self-determined decisions. Specifically, this means that counsellors do not dictate what someone “should do” or give advice on “what they think is right.” They help by listening to the clients, by reporting their own experiences, exploring possibilities and resources to be used with the person seeking advice, and then finding their own solutions.



# Recovery-focused mental healthcare

Jaime Essed, Founder and CEO of the company Oh My Mood, turns the spotlight onto Recovery-focused mental healthcare

In traditional healthcare, the term 'recovery' mostly has been used to refer to the end of a particular experience or episode of illness. From the biomedical perspective, health was regarded as a state of normal functioning that could be disrupted from time to time by disease. Recovery comprised the restoration of the body's ability to function, with full symptom-remission as a set outcome. However, in recovery-focused mental healthcare, 'recovery' covers a broader concept. The term does not refer to a set outcome of full symptom-remission, but to "a deeply personal, unique process of changing one's attitudes, values, feelings, goals, skills and/or roles. It is a way of living a satisfying, hopeful and contributing life even with limitations caused by the illness. Recovery involves the development of new meaning and purpose in one's life as one grows beyond the catastrophic effects of mental illness". Developed in 1993 by William Anthony, Director of the Boston Center for Psychiatric Rehabilitation, this definition of mental health recovery, has become one of the cornerstones of the recovery concept.

Central to the concept is that individuals with severe mental illness want and need more than just symptom relief. It also made clear that, when isolated from subjective experience, symptoms are inadequate to qualify personal mental health. Although it is a fact that severe mental illness

causes symptoms or mental impairments that can generate significant functional limitations, disabilities and handicaps, it has also been proven a fact that people can grow beyond the effects of mental illness. As the person moves on to other interests and activities they are no longer the primary focus of one's life. Successful recovery means that the person has changed his or her focus toward living a satisfying, hopeful and contributing life even with the limitations caused by the illness.

The main impetus for the development of the recovery concept came from the consumer/survivor/ex-patient movement during the late 1980s and early 1990s in the United States (U.S.). The main message was that there is no need nor right in approaching individuals with severe psychiatric disabilities as incomplete or failed and unnecessarily isolate or exclude them from society. Instead, they should be empowered to develop their potentials to meet their needs, wants and responsibilities and assert their rights to full citizenship as any other citizen. Be it quite slowly, the implications of this message for the mental health system became better understood. How service users could maintain the ownership and authenticity of their recovery while also supporting them in professional policy and practice currently has become a key issue in the mental health system of many countries.

Often, those with lived experience have described recovery as the journey of an individual as they grow within and beyond what has happened. Recovery is a personal journey in which individuals do not define themselves in relation to their symptoms and the mental healthcare services but in relation to their own life. During this journey, the patient develops a secure base and sense of self from which they can find new meaning in life and build coping skills and supportive relationships and social roles. This process is not linear but does tend to take place as a series of small steps, which can be continued even if symptoms later re-occur. The overarching message is that hope and restoration of a meaningful life are possible, despite serious mental illness. In this journey, it is not the professional who takes centre stage. This person may (or may not) have a marginal role.

Although recovery has emerged from the lived experience of people experiencing what professionals understand as mental illness, scientific research is catching up in its ability to validate the assertions of service users and their families. The professional literature began to incorporate the recovery concept from the early 1990s in the U.S. Fuelled by a number of long-term outcome studies of people with "major mental illnesses" in populations from virtually every continent, including landmark cross-national





longitudinal studies by the World Health Organization (WHO) in the 1970s and 1990s showing unexpectedly high rates of complete or partial recovery, it became clear that the population of people who are professionally seen in mental health services does not offer a representative picture of life following a diagnosis of mental health problems.

Based on growing empirical evidence, mental health services are increasingly focused on supporting long-lasting positive change in patients' lives and promote well-being through strengthening positive psychosocial characteristics in people who suffer from or are at high risk of developing mental or physical illnesses. From fixing what's wrong to building what's strong

became the credo under which flag professionals take their (modest) part in building resilience, optimism, personal mastery and coping self-efficacy, social engagement, spirituality and religiosity and wisdom (including compassion). A growing body of research shows that higher levels of these characteristics are associated with objectively measured better health outcomes including greater longevity, as well as with overall subjective well-being.

In general, recovery may be seen as more of a philosophy or attitude than a specific model, requiring fundamentally that people with mental illness regain personal power and a valued place in the community. Even when they sometimes need services to sup-

port them to get there, this doesn't mean that they should be silenced and cut off from their personal needs and wishes, or even from their personal wisdom. Recovery needs to address the whole of people's lives and to encourage aspirations while promoting equal access and opportunities within society.

It has been emphasised that each individual's journey to recovery is a deeply personal process, though being firmly related to an individual's community and society. A number of features or signs of recovery have been proposed as core elements and have been categorised under the concept of CHIME. CHIME is an abbreviation of Connectedness, Hope and optimism, Identity, Meaning & pur-

pose and Empowerment and building a secure base.

## Connectedness

A common aspect of recovery is said to be the presence of others who believe in the person's potential to recover and who stand by them. Since mental health professionals can only offer a particular and limited kind of relationship, relationships with friends, family and the community are of wider and longer-term importance. Others who have experienced similar difficulties, who may also be on a journey of recovery, can be of particular importance. Since recovery is not synonymous with a cure, a strong supportive network is required. It is said that one-way relationships based on being helped can actually be devaluing and that reciprocal relationships and mutual support networks can be of more value to self-esteem and recovery.

## Hope and optimism

Finding and nurturing hope has been described as a key to recovery. Hope doesn't include just optimism, but represents a sustainable belief in oneself and a willingness to persevere through uncertainty and setbacks. Hope may start at a certain turning point, or emerge gradually as a small and fragile feeling and may fluctuate with despair. It is said to involve trusting and risking disappointment, failure and further hurt.

## Identity

Recovery of a durable sense of self (if it had been lost or taken away) has been proposed as an important element. A research review suggested that people sometimes achieve this

by "positive withdrawal" – regulating social involvement and negotiating public space in order to only move towards others in a way that feels safe yet meaningful and; nurturing personal psychological space that allows room for developing understanding and a broad sense of self. This process is usually greatly facilitated by experiences of interpersonal acceptance, mutuality and a sense of social belonging; and is often challenged by the overt and covert negative messages that come from the broader social context.

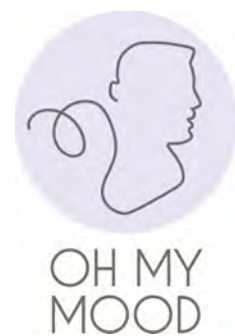
## Meaning and purpose

Developing a sense of meaning and overall purpose in life is said to be important for sustaining the recovery process. This may involve recovering or developing a social or work role. It may also involve renewing, finding or developing a guiding philosophy, religion, politics or culture. From a postmodern perspective, this can be seen as developing a narrative.

## Empowerment and building a secure base

For many, recovery has a personal as well as a political implication. Where to recover is to validate the self and find meaning; challenge prejudice (including diagnostic "labels" in some cases) and reclaim a chosen life and place within society. Recovery can, thus, be viewed as one manifestation of empowerment and self-determination to reduce the social and psychological effects of stress, develop the confidence for independent assertive living and building a positive culture of healing, overcoming social stigma and prejudice about mental disorder/difference and achieving social inclusion.

This may require recovering detached social skills and identity, making up for gaps in work history for better self-management, etc. It has been suggested that essential in the recovery approach are appropriate housing, sufficient income, freedom from violence and adequate access to healthcare. An empowerment model may emphasise that conditions are not necessarily permanent; that "symptoms" can be understood as expressions of distress related to emotions and other people and that other people have recovered who can be role models and share experiences.



**Jaime Essed**

**Founder and CEO**

Oh My Mood

Tel: + 44 (0)330 8382 554

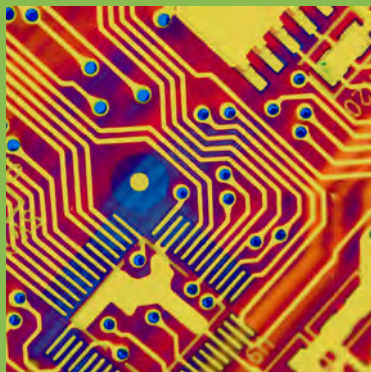
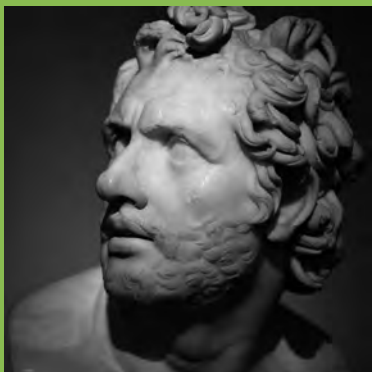
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# Cannabinoids for therapeutic purposes – where are we?

Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group shares a perspective on the present status and potential evolution when it comes to cannabinoids for therapeutic purposes

The controversy concerning the use of cannabinoids for therapeutic purposes due to their psychoactive properties is present in many countries, the reason for which their prescription for medical and research purposes may be restricted. Nevertheless, most researchers all over the world strongly emphasise in their value as therapeutics for various severely underserved medical areas (Velmurugan, 2018).

The most studied extracts from cannabis are phytocannabinoids (naturally occurring cannabinoids), cannabidiol (CBD), cannabidivarin and delta-9-tetrahydrocannabinol (D9-THC), which are the unique compounds that interact with the endocannabinoid system (ECS) by modulating a broad spectrum of physiological systems influenced by the ECS (Maroon and Bost, 2018). Indeed, the therapeutic potential and applications of both phytocannabinoids and endocannabinoids, are beginning to demonstrate promising results in different disease conditions, including medically uncontrolled epilepsy and refractory epilepsy, childhood seizure disorders Lennox-Gastaut and Dravet syndromes, Alzheimer's disease, Parkinson's disease, multiple sclerosis, chronic neuropathic pain, inflammation, glaucoma and even different types of cancers (Yasmin-Karim et al., 2018), as well as, psychiatric and mood disorders, such as schizophrenia, anxiety, depression, addiction, post-concussion syndrome and post-traumatic stress disorders. These observations have been substantiated by numerous studies. The National Academies of Sciences, Engineering and Medicine, for instance, conducted an exhaustive review of recent medical literature on The Health Effects of Cannabis and Cannabinoids (Abrams, 2018). This deep-dive work consisted of a systematic review process across over 10,000 studies.

Nevertheless, some concerns related to the healthy use of cannabinoids prevail among the clinical commu-

nity. Although a variety of CBD products are available in several countries, including the U.S. Food and Drug Administration (FDA) approved Epidiolex and the EU's European Medicines Agency (EMA) approved Sativex (also branded as Bedrocan, Marinol, and Cesanet), the legal status of the non-FDA/non-EMA approved products remains controversial. Moreover, non-FDA approved products present important variations among their consistency and quality, being in most cases difficult to establish whether their labelled CBD and D9-THC dosages are acceptable and to determine if the product is free of adulteration and contamination (White, 2019).

## Potential therapeutics and business opportunities

Due to preclinical studies across a wide range of therapeutic areas suggest the anticonvulsant effects of phytocannabinoids mediated by the ECS, such as CBD and cannabidivarin, their antiseizure effects are a matter of very exciting discussions. Endocannabinoids are cannabinoids synthesised normally within the central nervous system (CNS). In particular, they play a key role in decreasing the release of excitatory neurotransmitter in CNS, hence proposed for preventing seizures (Sidra et al., 2018). Most scientists remark the fact that CBD, in contrast to D9-THC, does not produce any euphoric/intrusive psychoactive side effect. For that reason, CBD and cannabidivarin have been proposed as an adjunctive treatment for epilepsy (Stockings et al., 2018). In fact, there are more than 500 clinical trials in different stages of validation associated with the study of CBD in human health. Nine studies (active, not recruiting) are undergoing Phase 3 and Phase 4 clinical trials, whereas another 32 studies are planned to start late-stage clinical trials in 2019 and 2020 proposing CBD as adjunctive therapy for treatment-resistant pediatric and adult epilepsies.

Regarding business, more than 1.9 million U.S. residents have prescriptions for medical cannabis in 30 states and the District of Columbia. The revenue from California alone was \$2.7 billion in 2017. The overall medical cannabis space is expected to grow at a CAGR of 13.6% from 2017 to 2022 to reach \$10 billion by 2022. Globally, the United States, Canada and Western Europe are key markets (Das, 2018).

**“Due to preclinical studies across a wide range of therapeutic areas suggest the anticonvulsant effects of phytocannabinoids mediated by the ECS, such as CBD and cannabidiol, their antiseizure effects are a matter of very exciting discussions.”**

## Final remarks

In October 2017, at Stanford University, the Cannabinoids in Epilepsy Therapy workshop was carried with the aim to open discussions about CBD based therapeutics among researchers, clinicians and patient advocates (Huizenga et al., 2018). The workshop facilitated a deeper knowledge around the current state of CBD, especially for the treatment of epilepsy, whereas aided the recognition of most concerning gaps that still needed to be addressed. Such scientific meetings engaging the community have gained increasing attention during the past two years. In parallel, the notorious augment of clinical trials advancing later stage status evidence the escalating interest in developing CBD preparations for the treatment of different conditions, mostly focused on epilepsy due to the observed efficacy without side effects. Big pharmaceutical companies working on the development of CBD-based drugs have the greatest potential to take the medical marijuana market to the next level because they have enormous amounts of capital, coupled with the regulatory process knowledge, to advance CBD-based therapeutics from clinical trial to marketed product. ■

## Acknowledgements

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**Cecilia Van Cauwenberghe, PhD, MSc, BA**  
**Associate Fellow and Senior Industry Analyst**

TechVision Group, Frost & Sullivan  
 cecilia.vancauwenberghe@frost.com  
 ww2.frost.com  
 www.twitter.com/Frost\_Sullivan

# UK and Ireland medical cannabis access programmes and education slowly progress

GreenLight Pharmaceuticals Ltd is advancing clinical research and education in UK and Ireland; Though government progress on access and prescribing recommendations lags behind much of Europe

## GreenLight and Medical Cannabis

Established in 2014, [GreenLight Pharmaceuticals Ltd](#) is an Irish biopharmaceutical company focused on developing safe and effective plant based medicines. GreenLight specialises in phytocannabinoid research and clinical development.

'Medical cannabis' (cannabis based medical products (CBMP)) refers to a range of [products](#) that contain active compounds (primarily  $\Delta^9$ -tetrahydrocannabinol (THC) and cannabidiol (CBD)), either synthesized chemically, isolated from plant, or raw plant preparations.

In the past decade Germany, Italy, France, Spain and Switzerland have implemented medical cannabis access programmes for particular indications (Figure 1). In 2018 Ireland and UK also permitted medical use, however the prescribing process is still nascent, restricting access and uptake.

This article briefly explores the current clinical evidence, issues in the UK and Irish patient access and medical education programmes, with GreenLight's plans highlighted.

## Clinical Evidence for Medical Cannabis

Albeit 'moderate' in nature, the strongest evidence of CBMPs clinical efficacy stems from systematic reviews

of randomised controlled trials (RCTs). Multiple sclerosis, pain and epilepsy are conditions consistently cited in government reports from [Europe](#) and [US](#) as the most appropriate to target with medical cannabis.

### Multiple Sclerosis (MS)

Standardised cannabis plant extracts of THC and CBD delivered in equal quantities (nabixomols) were the first CBMP to be licensed in the UK for MS-related muscle spasm and neuropathic pain. MS patients receiving nabiximols as an adjunct treatment report [reduced spasm](#) versus standard treatment. In 2014 nabiximols were licensed in Ireland, however the Health Service Executive do not currently deem it to be [cost-effective](#).

### Chronic pain

Chronic pain, including neuropathic and musculoskeletal pain is a major reason that patients cite for accessing medical cannabis in Canada and the [US](#). A 2018 Cochrane review reports a modest but significant increase in the proportion of patients who achieve a 30% [reduction in pain](#). GreenLight is optimising clinical trial designs to test cannabinoid combinations for pain in arthritis.

### Epilepsy

A 2018 systematic review, of intractable childhood epilepsy RCTs, concludes that adding CBD to conventional anti-epileptic drugs significantly

[reduces seizure frequency](#) (48.5% of patients reported 50%+ reductions in seizure frequency). GreenLight plan to add to the limited knowledge in this condition by conducting dose finding trials to minimise interactions with co-medications, in other forms of epilepsy.

GreenLight are already screening the efficacy of lesser studied cannabinoids from their cultivation programme in 3 core disease areas:

- Neurological conditions - Alzheimer's, addiction and pain.
- Inflammatory conditions- rheumatoid arthritis, arthritis-related depression, eye disease and diabetes.
- Cancer- of the prostate.

## Access Programmes and Medical Education

A range of medical cannabis regulatory frameworks and provision models are currently employed across Europe, with varying degrees of patient accessibility. As [UK](#) and Ireland have only recently approved medical cannabis, much progress is needed to operate as effectively as established European programmes (Figure 1). GreenLight Pharma is actively engaging regulators to improve patient access programmes. The current frameworks are briefly contrasted with Germany below.



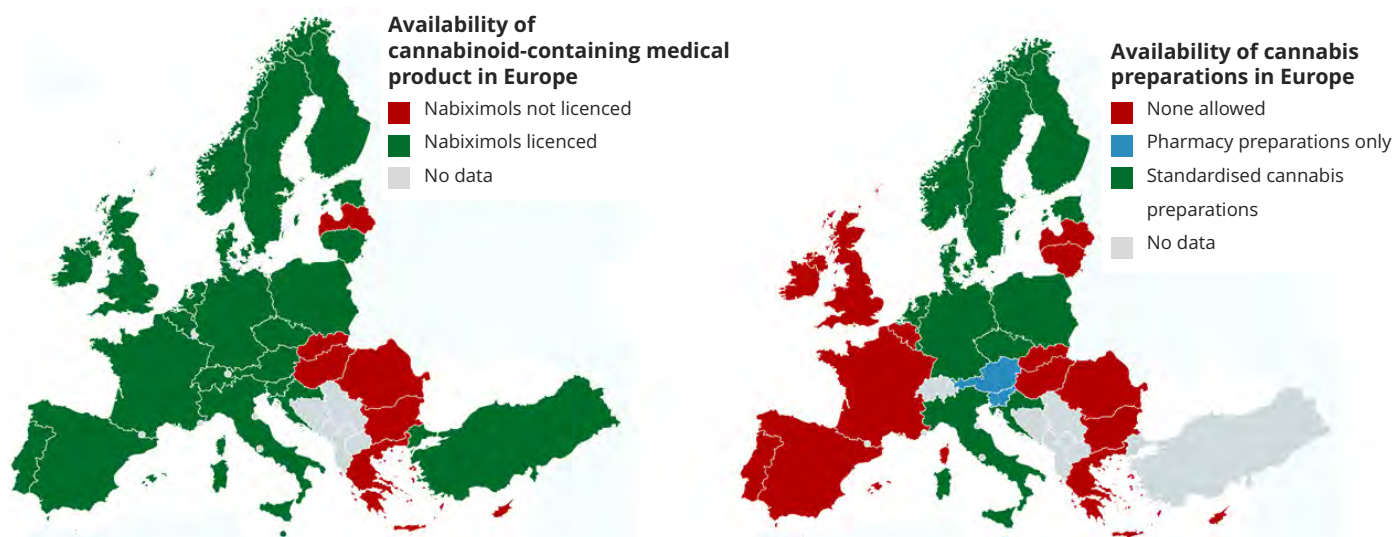


Figure 1: Availability of cannabinoid containing medical products and cannabis preparations in Europe

## United Kingdom

In November 2018 medical cannabis was moved from schedule 1 (no medicinal value) to schedule 2, allowing specialist doctors to prescribe for any condition, and for clinical research to be conducted. Since the reschedule, 18 private (no NHS) prescriptions for standardised plant preparations have been made. Doctors are wary to prescribe for a multitude of reasons including the modest evidence base, lack of NHS reimbursement and no NICE prescribing guidance (due Oct. 2019). Importantly, GreenLight's clinical trials will evaluate safety alongside clinical efficacy and cost effectiveness of CBMPs.

## Ireland

In 2017 a HPRA report recommended that medical cannabis should be prescribed in a limited number of medical conditions, where prior treatment has failed. Specified conditions include MS spasticity, intractable cancer nausea and refractory epilepsy. The Access Programme for medical cannabis is embryonic and currently limited in uptake. Prescribing doctors need to secure a licence for named patients from the Minister for Health. Irish supplies of medical cannabis have only

recently been secured, with a small number of patients permitted to use cannabis products from Netherlands. Announcement of a formal access programme is expected mid 2019.

## Germany

Germany has followed a similar legal framework to Netherlands with the 2017 Cannabis as Medicine act. Patients with treatment refractory conditions can access nabiximols, dried cannabis plant or standardised extracts prepared in pharmacies. Prescription is not limited to specialist doctors, nor for specific indications. Germany has tendered for domestic production of up to 2 metric tons of cannabis per annum to standardise the quality of supplies. GreenLight are developing cultivation licences in several countries in Europe and have secured supplier agreements to ensure sustainable, high quality supplies.

## Prescribing guidance needed

Training on CBMPs in the UK is yet to be commissioned by the NHS. In Ireland, the HPRA Medical Cannabis access programme have published detailed guidelines on CBMPs prescribing. Several medical profession organisations have developed clinical

advice on CBMPs. Complementing these efforts, GreenLight has compiled an online course on cannabinoid prescribing, which will be launched in autumn 2019.

It is clear that frameworks for medical cannabis access remain underdeveloped in the UK and Ireland. However GreenLight is actively leading improvements in medical training, prescription recommendations, standardised supplies and robust clinical trials to help develop access systems that fit regulatory requirements, while meeting patient and clinician demand for safe and effective medicines.



**David Gibson, PhD**  
**Chief Scientific Officer**

GreenLight Medicines (trading name of GreenLight Pharmaceuticals Ltd)  
david.gibson@greenlightmedicines.com  
<https://greenlightmedicines.com>  
[www.twitter.com/greenlightmeds](https://twitter.com/greenlightmeds)

# Cannabinoids in medicine

## Part 1: Cancer

In the first of a series of five profiles, Oxford Cannabinoid Technologies will be discussing their expertise on the medicinal use of cannabis derivatives, known as cannabinoids. This first piece will focus on the use of cannabinoids to treat cancer

The term 'cannabinoid' originally referred to a group of compounds found in the species of the cannabis plant known as *Cannabis sativa*.<sup>1</sup> Following the development of synthetic derivatives of cannabinoids and the discovery of natural endocannabinoids, the term 'phytocannabinoid' was given to cannabinoids obtained from cannabis plants.<sup>2</sup>

The best-known of these phytocannabinoids are tetrahydrocannabinol (THC) and cannabidiol (CBD) and two well-known cannabinoid receptors in the brain are CB1 and CB2. The CB1 receptor binds with THC and is thereby responsible for THC's psychotropic effects. Most if not all phytocannabinoids, however, act on more receptors than just these – the study of these compounds is, therefore, highly complex and their potential to treat a wide range of diseases is highly significant.

### Cannabinoids and cancer

The potential of cannabinoids to alleviate the symptoms of cancer and even treat its underlying causes has been discussed since pre-clinical research papers in the early 1970s demonstrated that the growth of lung tumours in mice could be slowed by THC and other cannabinoids.<sup>3</sup> While the ability of cannabinoids to alleviate the symptoms of cancer is widely accepted, pre-clinical studies suggest that cannabinoids may be effective in

the actual treatment of multiple cancer types (for instance glioblastoma multiforme<sup>4</sup> and prostate cancer<sup>5</sup>). Some studies have also affirmed that cannabinoids have a protective effect against certain types of tumours. Others suggest that cannabinoids can inhibit proliferation, metastasis and migration of cancer cells and even induce their death.

Despite these potential anticancer effects of cannabis, it is also important to note that, depending on the drug concentration, studies have found that cannabinoids can both inhibit and stimulate cancer cell proliferation;<sup>6</sup> more research must, therefore, be undertaken on the effects of cannabinoids on different tumour cell types.

### Anecdotal evidence

Beyond scientific studies, there have been several 'real-world' examples of cannabis having the potential to treat cancer:

- In June 2018, the Coventry Telegraph and Birmingham Mail reported on Joy Smith, a cancer survivor, who was given six weeks to live when she was diagnosed with cancer in her stomach and bowel. Now, two years later, she is close to receiving the all-clear after taking regular doses of THC cannabis oil;<sup>19</sup>
- In June 2018, the Express reported

on Garry Hill, 83, who claims CBD oil helped to shrink his tumour by half. His doctor was "amazed" his cancer had shrunk, said Hill, who is now in remission;<sup>20</sup>

- In April 2018, the Birmingham Mail reported on Lynn Cameron, who was given between six and eighteen months to live in 2013 after she was diagnosed with stage 4 brain cancer. When the doctors gave up, Lynn turned to CBD oil. Soon afterwards, her tumour started shrinking. By the sixth MRI, the cancer had gone;<sup>21</sup>
- And in February 2018, the Daily Mail reported on Dee Mani, 44, who refused chemotherapy when she was diagnosed with triple negative breast cancer – deemed the most lethal form – and opted instead to try cannabis oil. Doctors gave her the all-clear just five months after she did so.<sup>22</sup>

Given the growing body of pre-clinical research and anecdotal evidence, the potential curative properties of cannabinoids warrant significant further study. Cancer remains a key focus area for Oxford Cannabinoid Technologies, with multiple programmes already underway aimed at discovering new treatments for a range of cancer types. We look forward to sharing the learnings from these studies in due course.

## Key studies completed to date include:

Publication	Year	Finding
Oncogene <sup>7</sup>	2007	THC was found to inhibit epithelial growth factor-induced migration in lung cancer cells. The study emphasised that THC's potential in controlling the growth and metastasis of certain lung cancers should be further explored.
British Journal of Cancer <sup>8</sup>	2009	CB2 agonists were found to have reduced the proliferation of prostate cancer cells and a synthetic CB2 agonist (JWH-015) significantly reduced tumour growth in mice. The conclusion was that cannabinoids interact with CB2 receptors on prostate cells to inhibit cell division and metastasis.
Cancer Prev Res (Phila) <sup>9</sup>	2011	Harvard Medical School investigated the role of CB1 and CB2 receptors in lung cancer and concluded that CB1 and CB2 could be used to develop new therapies against lung cancer cells.
FASEB J <sup>10</sup>	2012	CBD was found to inhibit lung cancer cell invasion by upregulating expression of intercellular adhesion molecule-1 and tissue inhibitor of matrix metalloproteinases-1.
Molecular Cancer Therapies <sup>11</sup>	2014	The effects of THC and CBD on glioma cell lines were investigated, both alone and in combination with radiotherapy. Reductions in cell viability were observed with each cannabinoid and combining the two proved synergistic; dramatic reductions in tumour volumes were seen when both cannabinoids were used with irradiation. The data highlight the possibility that cannabinoids can prime glioma cells to respond better to ionising radiation, suggesting a potential benefit to glioma patients by using a combination of these treatments.
Carcinogenesis <sup>12</sup>	2014	Cannabigerol (CBG) was found to inhibit growth in colorectal tumours, as well as in chemically induced colonic carcinogenesis. The authors concluded CBG should be considered in both the prevention and cure of colorectal cancer.
Cancer Letters <sup>13</sup>	2016	A synthetic cannabinoid was found to downregulate ID1, a protein that controls metastatic progression in many types of cancers, in a mouse with salivary gland cancer. The authors concluded that the results suggest a novel approach for the treatment of patients with aggressive salivary gland cancer.
International Journal of Cancer <sup>14</sup>	2017	It was found that cannabinoid receptors GPR55 (a target of CBD) and CB1 (a target of THC) play different roles in colonic carcinogenesis – the former seems to act as an oncogene and the latter as a tumour suppressor.
Oncogene <sup>15</sup>	2018	Mice treated with a combination of gemcitabine and CBD for pancreatic cancer survived for nearly three times longer than mice treated with gemcitabine alone.
Biochemical Pharmacology <sup>16</sup>	2018	THC and CBD, used in combination with temozolomide, synergistically reduced the growth of glioma xenografts.
International Journal of Cancer <sup>17</sup>	2018	Targeting CB2 with a synthetic cannabinoid was found to induce cell death in cancer cells among multiple myeloma patients. The cannabinoid also reduced tumour growth in vivo and overcame drug resistance in the tumours. The authors concluded that cannabinoids can be used in the treatment of multiple myeloma.
SAGE Open Medical Case Reports <sup>18</sup>	2019	A patient with lung cancer, after declining chemotherapy and radiotherapy, presented with tumour improvement following self-administration of cannabidiol. The authors concluded that cannabidiol might have caused the tumour response.

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**John Lucas**  
**Chief Commercial Officer**  
 Oxford Cannabinoid Technologies  
 Tel: +44 (0)1865 304 040  
[press@oxcantech.com](mailto:press@oxcantech.com)  
[www.oxcantech.com](http://www.oxcantech.com)  
[www.twitter.com/OxCanTech](https://twitter.com/OxCanTech)



# The Academy of Medical Cannabis

Professor Mike Barnes, Director of Education at The Academy of Medical Cannabis shares his thoughts on the rescheduling of cannabis to a Schedule II substance in November of 2018 and access to medical cannabis prescriptions

Since the rescheduling of cannabis to a Schedule II substance in November of 2018, the weight of political opinion in the United Kingdom has clearly moved farther towards the view that cannabis-based medicines should be accessible for patients in need, especially in the case of a number of young children with severe disabling epileptic conditions.

As is well known, since November, access to medical cannabis prescriptions has broadly not improved and with regards to the now imposed inability of the Home Secretary to provide special dispensation for select cases as a result of the change in legislation, some have even argued that access has become more restrictive.

**“Supported by this deep level of expertise and providing a comprehensive set of learning materials, our courses will equip a global footprint of clinicians with the knowledge and confidence to operate with medicinal cannabis.”**

From March through late May, through a series of Health and Social Services Select Committee hearings, in addition to Mike Penning’s Urgent Question to the Secretary of State for Health and Social Services Matt Hancock and latterly the backbench debate on medical cannabis, clear arguments have been made in support of a solution.



Emerging from these discussions are a pair of notable issues that have hindered UK clinicians from more widely and readily adopting medical cannabis as a therapeutic option.

## **A lack of education**

Despite a global record of clinical experience in medicinal cannabis, there have not been the balanced learning resources available for clinicians in the UK to confidently educate themselves in this area. Practical matters such as what are treatable conditions and how to safely and effectively dose and prescribe for these conditions, need addressing.

## **Questions as to the evidence**

To date, there has been a lack of the particular kind of base of evidence

that is rigorously applied to clinical practice. Randomised control trials are broadly viewed as the standard required. While more research is underway to establish this level of evidence, RCTs are costly, relatively slow to perform and are essentially not the right model for the complex family of cannabis medicines. Critically, this approach does not address an immediate need for the treatment of a number of grave and otherwise hard-to-treat conditions.

## **The Academy of Medical Cannabis**

Predicting these issues and formed in advance of the rescheduling of medical cannabis, The Academy of Medical Cannabis undertakes not only to provide the necessary platform to better

enable clinical education in medical cannabis but also to define the leading standard in this education.

Authored and contributed to by some of the world's leading medical cannabis clinicians and academics, The Academy of Medical Cannabis provides research, evidence and clinical practice-based education.

**“With patients actively in need of the more effective therapies that medical cannabis can provide, raising awareness as to the current availability of educational resources and ensuring that clinicians pursue this education, is paramount.”**

As The Academy's Director of Education, I contribute my experience as a consultant in neurology and rehabilitation medicine, including that of helping young patients treat severe illnesses with medical cannabis. Also taking a critical role in informing our courses is Dr Dani Gordon, a double board-certified doctor in integrative medicine with nearly a decade of experience in practising cannabis-based therapies in Canada and the U.S.

Our team also includes a number of leading experts in other highly relevant fields, each with outlying training and experience in medical cannabis.

- Psychiatric expertise is provided by consultant psychiatrist, Dr Rebecca Moore;
- Complex neurological and elderly care expertise is provided by leading specialist, Dr Elizabeth Iveson;
- General practice and primary care expertise are provided by the vastly experienced, Dr Leon Barron GP;

- And, offering his expertise in chronic pain management is the consulting physician, Dr David McDowell.

Supported by this deep level of expertise and providing a comprehensive set of learning materials, our courses will equip a global footprint of clinicians with the knowledge and confidence to operate with medicinal cannabis.

From foundations through to advanced information on specific conditions and for specialised therapies, including guidance on how to safely and effectively dose and prescribe, it is a focussed and clinically relevant education explicitly for clinicians.

## The Evidence Base

Critically, in recognition of the question surrounding the evidence for medicinal cannabis, The Academy has built the ground-breaking Evidence Base research database, exhaustively cataloguing and analysing the history of the most relevant and high-quality research on cannabis and for cannabis-based therapies.

This tool, added to the body of direct clinical experience that supports our learning, creates an illuminating picture in terms of the weight of existing evidence. As we continue to build this database we will move even closer to establishing an indisputable basis of evidence for medicinal cannabis.

## Live seminars

In addition to our online learning content, The Academy is now also offering live seminars in order to further improve access to clinical education in medical cannabis. Our first live event is to take place June 27th at the King's College London

Anatomy Theatre and will be led by myself, Dr Gordon and Dr Barron.

While tailored for clinicians, we would welcome policymakers and other relevant stakeholders to attend so as to understand the breadth and quality of The Academy's teaching. Please [register](#) if you wish to attend.

It is critically urgent that the issue of access to medical cannabis be resolved by removing the obstacles detailed here. With patients actively in need of the more effective therapies that medical cannabis can provide, raising awareness as to the current availability of educational resources and ensuring that clinicians pursue this education, is paramount.



**Professor Mike Barnes**  
**Director of Education**

The Academy of Medical Cannabis  
Tel: +44 (0)20 3928 2811  
[contact@taomc.org](mailto:contact@taomc.org)  
[www.taomc.org](http://www.taomc.org)  
[www.twitter.com/educate\\_taomc](https://twitter.com/educate_taomc)

# What is CBD and how does it work?

Savage Cabbage Ltd offer their expertise to explain what cannabidiol (CBD) is and how it works, here

**C**BD is short for cannabidiol, it is a critical phytocannabinoid found in hemp known for supporting the body and mind in many ways. It is not to be confused with oil from hemp seeds which does not contain cannabinoids.

CBD does not come from marijuana, it comes from hemp plants. Hemp and marijuana are close relatives but are not the same, by definition hemp contains no more than 0.3% THC (Tetrahydrocannabinol) the psychoactive compound found in higher concentrations in marijuana. Hemp naturally has higher levels of CBD, a non-psychoactive compound known for helping human bodies maintain health and overall wellness and has no psychoactive effect.

There has been an almost exponential growth in the number of different CBD oils and hemp extract products available in the market place, purely as a result of people seeing positive effects in their health and wellbeing after using this health supplement in the daily dietary routine.

The best quality CBD oil products are derived from whole hemp plant extract with a full spectrum cannabinoid content with other cannabinoids and beneficial plant compounds like terpenes and flavonoids. It is believed that using whole plant maximises benefits derived throughout the body and supplies additional wellness components.

## How does CBD work?

Decades of research have shown phytocannabinoids (CBD) to be a potent aid in supporting overall wellbeing in human bodies, achieved when CBD enhances the Endocannabinoid System (ECS).

## What is the Endocannabinoid System (ECS)

The ECS was discovered in the 1990s and is thought to be one of the most vital and vast receptor systems for sustaining good health and has been recognised as an important modulatory system in the function of brain, endocrine and the immune tissues.

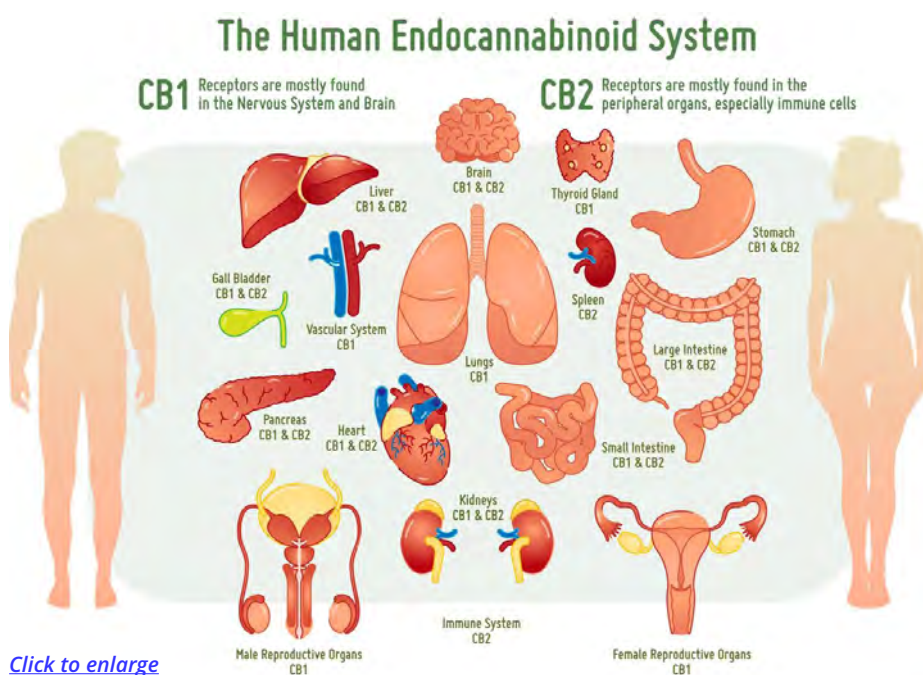
Recent science has found that the ECS does not only respond to Endogenous cannabinoids produced in the body, but also responds to external Phyto-

cannabinoids or CBD as a means of enhancing the bodies ECS function.

Within the ECS there are receptors CB1 and CB2, located throughout the body. These neurons are a sort of lock, with cannabinoids acting as the key. CB1 receptors exist in high numbers in the brain, especially in the Hypothalamus, Hippocampus and Amygdala. CB2 receptors occur most commonly in the spleen, tonsils, thymus and the immune cells. The endocannabinoid system plays an import role in homeostasis.

## What to consider before buying your CBD products

Traceability is an important factor to take into consideration when looking for a product to buy, as the hemp plant which is renowned for cleaning





soil, was used in the process of cleaning the contaminated soil around Chernobyl (location of the world's worst nuclear disaster). The results have been so remarkable that Japanese scientists considered using it as part of their clean-up process for the Fukushima disaster, however, the difficulty obtaining hemp licenses prohibited them from using this miraculous plant.

Why mention this? It is important to remember that (for the same reason hemp is amazing at cleaning soil and pulling out heavy metals) the consumer ensures the products they are considering buying are quality hemp extract products that are responsibly grown with great agricultural care, preferably with a good manufacturing practice (GMP) accreditation such as that which has been awarded to CW Hemp (Charlotte's Web Oil).

Before you buy a CBD product, consider using the following checklist:

- Make sure the manufacturer controls the process from farm to shelf and uses quality raw materials to start with.
- Ask if they do their own extraction.
- If they don't do their own extracting, ask who does and what method/solvent they use for extracting.
- Request batch testing Certificates of Analysis (C.O.A.) carried out by independent third-party analysis, to make sure there are no traces of contaminants, toxins or heavy metals.

These are the questions we asked when looking for a quality whole plant hemp extract to stock in our [shop](#). The questions were asked as a conse-

quence of Savage Cabbage CEO Jade Proudman undergoing a number of major operations which took their toll on her, and we realised there was a need to enhance her wellbeing and improve her homeostasis.

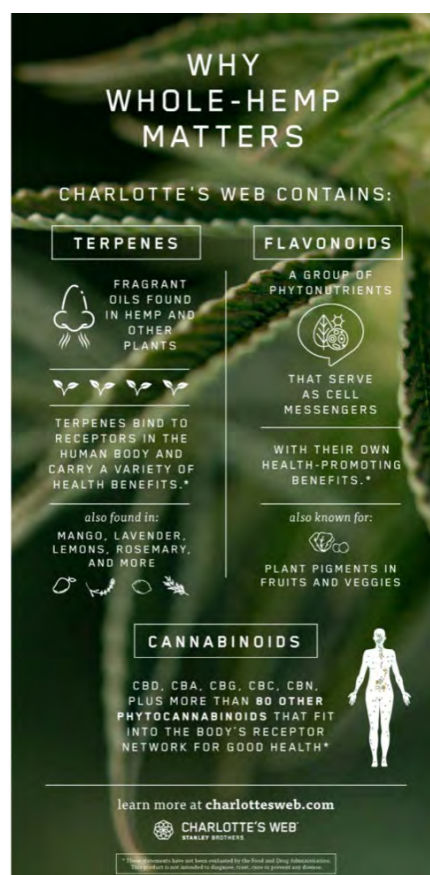
We discovered that Charlotte's Web Oil is a full spectrum hemp extract, more than just a CBD oil, with many beneficial compounds that come from their plants containing more than 80 other phytocompounds including Cannabidiol (CBD) Cannabigerol (CBG) Cannabichromene (CBC) along with Terpenes and flavonoids.

Available from [savagecabbageltd.com](http://savagecabbageltd.com)

## What are terpenes and flavonoids?

While terpenes and flavonoids are not cannabinoids they are compounds found in hemp and other plants.

[Click to enlarge](#)



Terpenes are fragrant oils that bind to receptors in the human body and carry a variety of health benefits; flavonoids are groups of phytonutrients that serve as cell messengers with their own health promoting benefits.

All the component parts working together produce what scientist have named the "Entourage effect".

## What is the entourage effect and why is it important?

When researching the benefits of cannabinoids, or CBD and whole plant extracts, you may have seen mention of the "entourage effect" but what does that mean, and why is it important.

The entourage effect is the results/effect produced from the synergistic interaction of the cannabinoids, flavonoids, terpenes and fatty acids naturally found in hemp. The entourage effect refers to the beneficial effect of all these compounds working together as opposed to just one or two of these compounds working in isolation.



Savage Cabbage Ltd  
Tel: +44 (0)175 147 1491  
[info@savagecabbageltd.com](mailto:info@savagecabbageltd.com)  
[savagecabbageltd.com](http://savagecabbageltd.com)



# Why cannabidiol (CBD) really is the next big thing

From the stories appearing about cannabidiol (CBD) and its near miraculous effects, to the pharmaceutical companies rushing to catch up, it seems everyone is taking about cannabidiol

**T**he buzz around cannabidiol (CBD) is loud because it can help so many diverse conditions; from cancer and back pain to anxiety and ADHD, but because it is so new to the UK, it can be hard to separate fact from fiction.

### What is cannabidiol?

CBD is cannabidiol, one of the two main substances found in cannabis plants. The other, THC, is what gives marijuana its high and is a psychoactive drug. CBD works on the body and has no psychoactive effect. CBD was legalised in the UK last year, provided it comes from EU approved plant strains and any THC has been removed. As we'll see, these guidelines are not always followed.

Once the preserve of Californian hippies, today you'll find CBD everywhere from the high street to specialised online retailers and there is a growing lobby who want to see it available on prescription. Following a Home Office decision to make certain cannabis-derived medicines available to patients with "exceptional clinical need", Home Secretary Sajid Javid admitted that "our position on cannabis-related medicinal products was not satisfactory." So CBD is headed for the mainstream.

### Does cannabidiol live up to the hype?

CBD can help alleviate chronic pain and reduce inflammation. Anthony Atterbury, a decorated West Midlands fireman suffers from primary progressive multiple scler-



rosis (PPMS) and the combination of pain and reduced mobility left him unable to walk or stand. "It has taken a lot of mental strength to go from leaping up and down ladders to being housebound," he says. Today he reports a 70% reduction in pain and believes that with continued use, he will one day walk again.

Many people are also using CBD to fight cancer and the side effects of treatments like chemotherapy. According to the American Cancer Society, "cannabinoids such as CBD slow growth and/or cause death in certain types of cancer cells growing in lab dishes."

Overall, both anecdotal evidence and a growing number of clinical trials show that CBD has real potential and there is no doubt you'll hear more in the coming months, especially as it's not just for those with serious illnesses. A growing number are using it to help them deal with minor ailments and lifestyle needs.

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**"The very best CBD is made in the U.S. from special plant strains with the right genetics and is gently extracted to preserve all the beneficial chemicals which are naturally present but stripped out by the harsher, industrial extraction used in cheaper products. Look out for full spectrum CBD and buy from a company that has traceable, tested products."**

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If you work out regularly, CBD is great post-workout recovery and as it's natural, it has none of the side effects of the typical recovery drinks, pills and powders. Shaun Perry, a boxer, martial artist and weight trainer for 16 years reported that after taking CBD Virtue's CBD: "I can feel the difference right away, even my sleeping pattern is better."

For smokers, CBD has been found to reduce cravings and can help you quit. It has a soothing effect, which has helped people suffering from everything from anxiety to epileptic seizures. As it is considered safe for children, parents are using CBD as an alternative to Ritalin and other ADHD medicines.

### **What makes good cannabidiol?**

Not all CBD is created equal. Plenty of unscrupulous companies are jumping on the bandwagon. As one of

America's biggest producers, John Merritt, explains: "It's common to find cheap Chinese CBD, watered down with labels claiming it is high strength and untested products with no CBD at all in them. It's the wild west."

The very best CBD is made in the U.S. from special plant strains with the right genetics and is gently extracted to preserve all the beneficial chemicals which are naturally present but stripped out by the harsher, industrial extraction used in cheaper products. Look out for full spectrum CBD and buy from a company that has traceable, tested products.

CBD is available in a bewildering range of products, including creams, oils, tinctures and edible treats like gummy sweets and honey sticks. Recently, Coca Cola announced they were looking at producing a CBD drink. CBD is also available in many different dosages and it can be hard to know how much to take and when. For most people, a daily dose of 10mg to 25mg is ideal and the best way to take CBD is through an edible product like gummies, honey sticks or a tincture.

CBD will continue to hit the headlines, as ever more effective products become available and more clinical trials are done to prove its effectiveness. ■

### **Henri Sant-Cassia**

CBD Virtue

Tel: +44 (0)20 3092 3261

[info@cbdvirtue.co.uk](mailto:info@cbdvirtue.co.uk),

[www.cbdvirtue.co.uk](http://www.cbdvirtue.co.uk)

[www.twitter.com/cbdvirtue](https://www.twitter.com/cbdvirtue)



# CBDepot: Producing natural cannabinoid ingredients

CBDepot, a pioneer in the production of high-quality natural cannabinoid ingredients and a world-leading researcher highlights the work they conduct here

The company, CBDepot, with roots dating to 2014, has been a leader in helping to establish legal and quality standards for cannabinoid ingredients and the formulation of cannabinoid derivatives that have a fast-growing presence in sectors including food, cosmetics, pharmaceuticals and other health products.

Our mission to provide upmarket cannabinoid ingredients in forms of isolated substances, whole plant extracts and compounded preparations for the industrial and consumer markets is driven by our belief that

cannabinoid-based products can contribute not only to medical care in a broad and complex therapeutic range but is also a small-dose aid that can improve well-being among consumers.

With science being a factor critical to our business, our research team is constantly probing the edges of cannabidiol. And in addition to CBD, we conduct R&D in isolation and synthesis of other cannabinoids such as CBG, CBN, CBC, D8-THC, CBDA and THCA, which we predict will generate great market interest in near future. Our science is anchored in CBDepot's

strategic affiliation with the Prague Institute of Chemical Process Fundamentals (ICPF) at the Czech Academy of Sciences.

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**"We strongly believe there is no room for health or medicinal claims for CBD in free access end user products, and work diligently with governmental agencies to develop rules for marketing and health claims on CBD-based consumer products."**

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Our activities also extend to the development of extraction and purification technology as well as scientific analysis

## Cannabinoid products

The products in our portfolio include:

**(-)-trans-Cannabidiol** (CBD >98%), derivative of industrial hemp (*Cannabis sativa* L.) for professional use in e-liquids, and skin-care products with properties as an antioxidant and antiseborrheic, and for skin conditioning and protection.

**Cannabigerol** (CBG >95%), industrial raw material for professional use only. A derivative of industrial hemp (*Cannabis sativa* L.)

**(-)-trans-Cannabidiol**, GMP (Cannabidiolum), a pharmaceutical raw material. For pharmaceutical use only. This product is manufactured, handled and stored in accordance with Good Manufacturing Practice (GMP) and as outlined in the International Conference on Harmonization „ICH Q7 guideline on Good Manufacturing Practice for Active Pharmaceutical Ingredients“.

Substance of choice, public tender winner in 2017 and 2019 for paediatric hospital and Institute of Oncology in Ljubljana.

This Active Pharmaceutical Ingredient is available for your clinical trials, pharmacy-compounded preparations or medicinal products.

Hemp Flavoring Preparations (THC-free), industrial hemp (*Cannabis sativa* L.) derivative from a mixture of CBD and CBG-rich extracts, fractionized during THC removal. Phytocannabinoids: 50% standardized, fully decarboxylated CBD and CBG ratio as per customer specification or 10% CBD/CBG in oil or 5% CBD/CBG in powder. Flavoring preparations as per EC/1334/2008, Art. 3.2(d)(i)



critical to development of our product lines.

CBDepot has been a leading participant in the development of a fair and responsible regulatory environment for CBD through its work with the European Union (EU), the United Nations Commission on Narcotic Drugs (CND) the World Health Organization (WHO), and the Foundation for Alternative Approaches to Addiction (FAAAT). Our leadership in working groups of the European Industrial Hemp Association (EIHA) has given us deep knowledge of the wider socio-economic aspects of our industry.

We have long been active in broader research on hemp under Slovak government licenses, and ultimately helped to push the Slovak government to adopt EU hemp-related farming rules in 2008. Through our affiliation with Hemp Seed Oil Europe, Ltd., a widely recognised European player, we've distributed Canadian hemp seed ingredients for the food, feed

and cosmetics markets in the EU on a large scale since 2009. That business has given CBDepot a profound appreciation for food safety legislation, and for regulations governing food supplement and health claims.

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**“Our mission to provide upmarket cannabinoid ingredients in forms of isolated substances, whole plant extracts and compounded preparations for the industrial and consumer markets is driven by our belief that cannabinoid-based products can contribute not only to medical care in a broad and complex therapeutic range but is also a small-dose aid that can improve well-being among consumers.”**

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As the regulatory framework for hemp CBD extracts and tinctures in foods continues to unfold, CBDepot has been a leader in working to establish progressive rules for this important sector; and we have lent our expertise to the ongoing efforts to establish EU-wide regulations on allowable levels of THC in foods.

We strongly believe there is no room for health or medicinal claims for CBD in free access end user products, and work diligently with governmental agencies to develop rules for marketing and health claims on CBD-based consumer products.



**Michal Tózsér**  
CBDepot s.r.o.  
Tel: +421 911 920 888  
michal@cbdepot.eu  
www.cbdepot.eu

# Fundación CANNA: Promoting research, scientific studies and cannabis analysis

Here, we find out about Fundación CANNA's aim is to promote research and education about cannabis, including their strong focus on the effects of this on the human body

**F**undación CANNA (The Foundation) is a non-profit organisation founded in 2012 by CANNA España SL, a multinational company that produces high-quality fertilisers for fast-growing plants. Its headquarters is located in Barcelona, Spain. It has its own laboratory at the University of Valencia where it carries out cutting-edge research on cannabis and its compounds and performs different types of analytical chemistry tests.

Fundación CANNA believes that everyone has the right to know what they are consuming. It also considers that it is essential to support and fund research projects aimed at studying the active principles of cannabis and provide information that helps people to minimise the risks entailed in its consumption.

Fundación CANNA's aim is to research and study the cannabis plant and its compounds to educate and inform people in a way that is easy to understand and always based on science.

The idea behind Fundación CANNA was conceived from the need to respond to the great demand for quality control in cannabis testing and to expand research to address scientific problems. The foundation particularly focuses on promoting studies and scientific research on the effects of cannabis on the human body.

The Foundation's ongoing mission is

to inform people and to support the worldwide medical cannabis movement. It regularly publishes new content on its website in collaboration with scientific researchers and distinguished members of the cannabis community.

It is a key for the Foundation to share knowledge about the cannabis plant and, in particular, the endocannabinoid system in humans and all related subjects. It invests a great deal of energy into making cannabis users aware of the importance of testing cannabis, oils and derivatives using scientific methods. People still require a lot of education about cannabis and the endocannabinoid system in the human body and the potential therapeutic use of cannabinoids in medicine.

Fundación CANNA's website, therefore, offers various articles on cannabinoids, terpenes, flavonoids, the endocannabinoid system, reports about the dangers of contaminants such as heavy metals and also the nutritional benefits of hemp seeds, etc. Readers can also find studies that the foundation helps to fund and organise on medical cannabis users' health and quality of life, studies on microbiological contamination, methods for quantifying cannabinoids and variations in terpene profiles in different cannabis strains. There is also plenty of content on the plant's possible therapeutic applications, as well as risk prevention

and interviews with the most distinguished members of the scientific community. All this content is written by active experts and researchers.

The foundation has also produced [brief informative videos on cannabis and the endocannabinoid system](#) to reach the public.

Fundación CANNA has supported several scientific associations and events, such as the International Association for Cannabis as Medicine (IACM), the International Cannabinoid Research Society (ICRS), the Spanish Cannabinoid Research Society (SEIC) and other important scientific events around the world.

It also co-produced the documentary "The Scientist" about the life of Dr Raphael Mechoulam, who has been awarded several international awards and recognition for his work.

The Foundation has Facebook and Twitter pages and a YouTube channel to reach the general public and cannabis users to provide them with quality information and to react to the large quantity of misleading information on social media.

Fundación CANNA's analytical testing services are intended for internal studies and for European companies that want to analyse their medicinal products based on cannabis or industrial hemp. It works according to the





“Cannabis and hemp oils and extracts have become very popular all over the world. However, due to the lack of regulations and standards, contamination and other impurities are often found in the oils.”

ISO 17025 standard, which guarantees the best possible analytical quality. The foundation is convinced that it is imperative to analyse cannabis to promote greater safety for users and to guarantee quality to consumers, which should be the goal of all companies and entities that operate in this market. It believes that there is a need for regulation at the European level regarding cannabis analytics, which is one of the Foundation’s future projects. It can also use all of these results to promote internal cannabis studies and to identify trends in the market.

It has carried out a wide range of tests in its laboratory, such as preparing cannabinoid profiles to determine their potency. The laboratory’s foundation can identify and quantify nine cannabinoids by HPLC and soon it will incorporate new ones.

Terpene analysis enables plants to be selected that are best adapted to individual needs and, based on the

proportion of terpenes present, to identify and classify the varieties more accurately than by simply assigning names or definitions such as Indica or Sativa.

Cannabis and hemp oils and extracts have become very popular all over the world. However, due to the lack of regulations and standards, contamination and other impurities are often found in the oils.

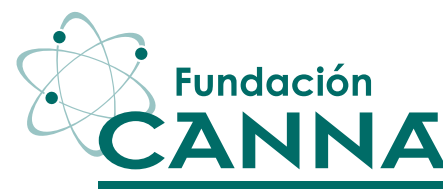
That is why the Fundación CANNA offers analytics of microorganisms, heavy metals and pesticide residues, to detect possible impurities, potentially harmful, in these products.

This is especially important in the case of extracts since the cannabinoids and also pesticides residues present in the plant material are concentrated in them.

All the funds raised by donations and the commercial laboratory testing

service are invested in supporting initiatives related to medicinal cannabis and funding new research around the world.

If you are interested in the Fundación CANNA’s activities, would like to suggest new studies or contribute to helping the Foundation to achieve its aims, please visit its website [www.fundacion-canna.es/en](http://www.fundacion-canna.es/en) or email: [info@fundacion-canna.es](mailto:info@fundacion-canna.es)



Fundación CANNA  
[info@fundacion-canna.es](mailto:info@fundacion-canna.es)  
[www.fundacion-canna.es/en](http://www.fundacion-canna.es/en)

# Regulation and quality control for the medical cannabis industry

AlphaCAT (Cannabinoid Analysis Test) takes the first step to regulation and quality control for the medical cannabis industry, as this profile by the firm's Sebastien Beguerie sheds light on

**A**lphaCAT (Cannabinoid Analysis Test) is based on the principles of chromatography analytics. Chromatography means in Greek "marked colour" as laboratory techniques to separate a complex mixture. In the world of herbal remedies by the use of the phyto-therapy producer and physicians, they need to understand the difference between the chemical compound inside each herb. Because medicinal plant contains more than one active compound, it is essential for the botanist and manufacturer to know the exact composition of these plants.

The cannabis plant is now becoming recognised for its medicinal value through its active compound called "cannabinoids". Today, it has been discovered that there are more than 500 compounds inside cannabis with 110 cannabinoids. These cannabinoids can be identified as family clusters with these six main cannabinoids:

- Cannabidiol (CBD).
- Cannabiniol (CBN).
- Delta-9-Tetrahydrocannabinol (THC).
- Tetrahydrocannabivarin (THCV).
- Cannabigerol (CBG).
- Cannabichromen (CBC).

Each of these cannabinoids will pro-

duce a different effect according to their pharmacognosy. Therefore, each cannabis chemo-type can have a different therapeutical value. In that regard, knowing the phytochemical composition of cannabis dried flower and its derivate plays a major role in preparing and delivering the standard dosage of phytocannabinoid to patients.

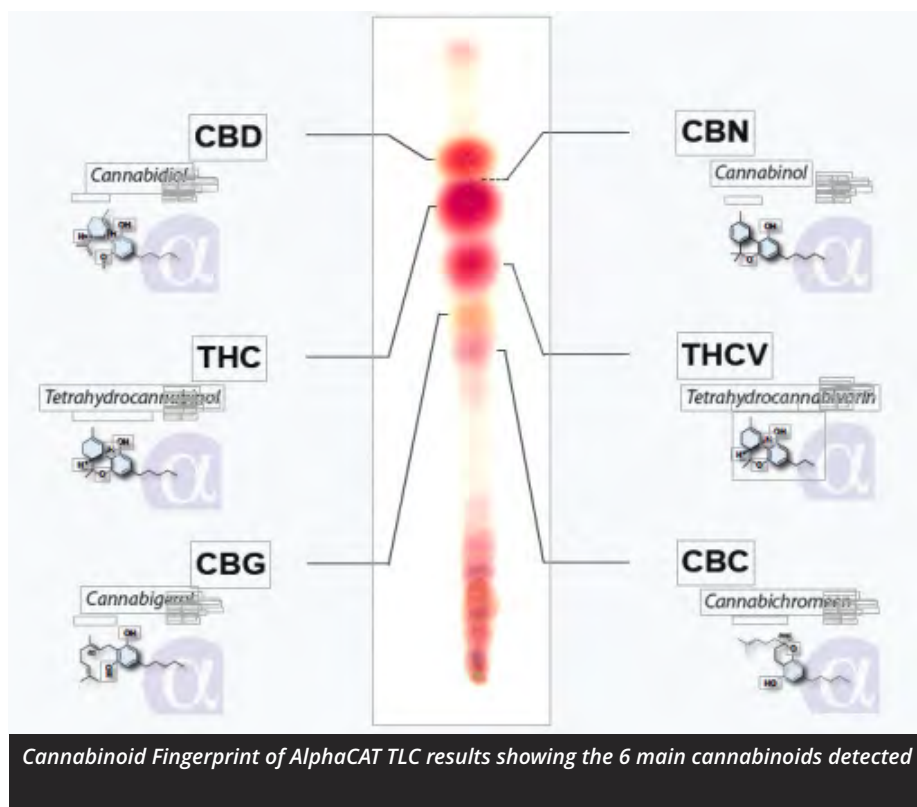
**"The AlphaCAT TLC method is innovative as the first commercialise kit to be able to qualify and quantify cannabinoid content in cannabis and its derivate. It is done in five steps and takes half an hour to perform. It is ideal for pharmacist and herbalist to be used for their herbal cannabis preparation to know the dosing of their final product."**

The cannabis plant belongs to the smallest family in the plant kingdom, called the "Cannabinaceae". In this family, there are only two plants, cannabis and hop that are among the most used plant on earth. From the Cannabis sativa L variety, it has evolved into numerous biotype cultivar existing in almost all latitudes on the planet. These biotype cultivars from India, Africa, to South America, have developed in adaptation to their environment a large number of compounds to allow its survival in hostile location. Nowadays, breeding has taken place in crossing all these different cultivars by creating new chemovars with unique cannabinoids profile for the medicinal industry.



*Sebastien Beguerie, AlphaCAT Founder in one of his consulting greenhouse's client*

In order for producer, manufacturer and physicians to create the best cure for patients, they need to be able to assess the phytochemical composition of cannabis and their cannabinoid profile. The methods used to analyse these divers' molecules are done using chromatography techniques. It exists as three main chromatography techniques done by gas, liquid or thin-layer separation. The gas and liquid chromatography required expensive machinery with the need of high-educated post-graduate staff. These machines can cost more than a prestigious luxury car. On the other hand, thin-layer chromatography (TLC) is inexpensive and easy to use by anyone who can follow a cooking recipe.



In the pharmaceutical practices for production of cannabinoids, quality control checks have to occur in every stage of the manufacturing process to achieve the highest standards for production in order to obtain a robust and consistent product. The manufacturer needs to guarantee from every batch produced the cannabinoid content, the uniformity, chemical and physical stability, with its biological availability.

**“The cannabis plant is now becoming recognised for its medicinal value through its active compound called “cannabinoids”. Today, it has been discovered that there are more than 500 compounds inside cannabis with 110 cannabinoids.”**

Official document guidelines regarding quality control often recommend more than one analytical method to be used. It is always recommended to seek for more testing methods to verify one from another to assure

reproducibility with qualitative and quantitative assessment of the phytochemicals present. For cannabis and its cannabinoid analysis, different methods are being recommended by the United Nation on Drugs and Crimes (UNODC) report from 2009. In this report, a large section is dedicated to the TLC method as a quick way for law enforcement and forensic investigation to address the cannabinoid profile of cannabis seize during police control.

In this sense, in 1980, a scientific publication order by UNODC and conducted by Baker et al showed the difference in cannabinoid profile of cannabis coming from different parts of the world from South America, Africa, India and Asia. For each of the continent, it was possible to identify its origin from their cannabinoid ratio with THC/THCV, CBD/THC, CBG and CBC. They concluded that TLC: “TLC examination is a valuable indicator of the country of origin where there are no characteristic

physical features, for instance, in the analysis of small amounts of material or in the case of liquid cannabis.”

Since 2016, in Switzerland and in Europe, retail shops have started to commercialise cannabis flowers with less than 0.2% THC with a high concentration of CBD and other derivate CBD products. Due to the THC content below the legal limit, it cannot be considered as a narcotic substance. But their physical aspect looks the same as narcotic cannabis with THC above 0,2%. That’s why it is becoming crucial for law enforcement to have a robust and accurate analytical method to run cannabinoid profile of cannabis flower taken from the street to know whether it is an illegal or legal cannabis flower. The AlphaCAT TLC test kit can assist the authority to make sure their investigations are made on illegal trafficking and not on legal goods sold by legitimate registered companies. The TLC AlphaCAT method can test for cannabinoids in dry flower, in Haschich, in





AlphaCAT Mini test kit  
for 8 tests

ment body to make the difference between narcotic and non-narcotic cannabis. In a regulated cannabis market, it is a great kit to know the truth about product labelling and make sure the dosage they claim is real in their product.

extract, in oil and other forms of secondary products.

**“Since 2016, in Switzerland and in Europe, retail shops have started to commercialise cannabis flowers with less than 0.2% THC with a high concentration of CBD and other derivate CBD products.”**

From the herbalist approach of using medicinal plant given to a patient in a phyto-therapy treatment guideline called ‘Monograph’ are being published for every plant belonging to the pharmacopaea. Monograph is written to guide the manufacturer and pharmacist to know which part of the plant can be used, how it should be grown, harvested and prepared in respect to quality control for final galenic preparation.

Until six years ago there was no modern monograph for medicinal cannabis. In 2013, the American Herbal Pharmacopaea (AHP), one of the most well-known institutes in monograph publications published

an official monograph on medical cannabis written by an expert in the field, like Professor Mahmoud ElSohly and Professor Ethan Russo. In their section dedicated to analytical, the first chapter is about TLC where they describe how it suits for the identification of primary cannabinoids, as well as to distinguish between THC-dominant, CBD-dominant and fibre type.

The AlphaCAT TLC method is innovative as the first commercialise kit to be able to qualify and quantify cannabinoid content in cannabis and its derivate. It is done in five steps and takes half an hour to perform. It is ideal for pharmacist and herbalist to be used for their herbal cannabis preparation to know the dosing of their final product. It is a great tool for the manufacturer to do their in-house quality control to assess their hazardous analytical control point for cannabinoid check in order to produce a standardised product. The AlphaCAT TLC kit can also be used by a governmental institute dealing with cannabis regulation to equip their law enforce-

To conclude, the AlphaCAT TLC test kit for cannabinoid analysis opens the path for the first step to regulation and quality control for the government, a licensed producer, physicians and patients to make sure of the safety and quality of cannabis product being consumed in this new emerging industry of medical cannabis.



**ALPHA-CAT®**

**Sebastien Beguerie**

Alpha-Cat.org  
Tel: +420 (0)7777 28845  
info@alpha-cat.org  
alpha-cat.org

# We need to talk about access to medical cannabis

Ramya Sriram, Digital Content Manager at Kolabtree, explains why many patients in the UK still cannot access medical cannabis and how scientific communication and further research can lead to change

Cannabis is widely known as a psychoactive drug that causes consumers to feel high, due to the cannabinoid tetrahydrocannabinol (TCH). Recreational use of the drug can cause dangerous side effects, which explains the negative stigma associated with it.

However, another cannabinoid in cannabis, cannabidiol (CBD), can have positive therapeutic effects and is causing countries around the world to legalise the drug's use for medical purposes.

On November 1, 2018, a change in UK law allowed specialist doctors to prescribe medical cannabis. Prior to the change, medical cannabis was classed as a schedule one drug under the Misuse of Drugs Regulations 2001, which meant it was not recognised to have any therapeutic value. After the change, it became a schedule two drug, meaning it has a recognised medical use and can be prescribed for certain conditions. This is an important step towards improving access to medical cannabis, but much more needs to be done.

## The first hurdle

Although medical cannabis is now legal in the UK, it is still unlicensed. This means patients must meet very specific criteria to be eligible for a medical cannabis prescription. Only adults and children with a severe form of epilepsy and adults with vomiting or nausea caused by chemotherapy can be prescribed the drug and only if their needs cannot be met by any other licensed medicines. Therefore, of the many patients who could benefit from medical cannabis, only a small proportion can be prescribed.

Even some patients who meet the criteria for a medical cannabis prescription may still not be prescribed it, due to doctors' reluctance to prescribe a drug they are

not experienced with. In October 2019, the [National Institute for Health and Care Excellence \(NICE\)](#) will publish new guidelines that may provide doctors with the information they need to confidently prescribe medical cannabis. Alongside new guidelines, we also require better communication with UK doctors about existing information on the drug. Also, ongoing research must remain a focus to increase our knowledge of the drug's efficacy, safety and the patient populations it may benefit.

## Supply and demand

The UK is the world's main producer and exporter of cannabis-based medicines. According to the International Narcotics Control Board, the UK produced 95 tonnes of cannabis in 2016, which accounted for almost 50% of the world's total production. Despite the country's leading position, many patients in the UK with signed medical cannabis prescriptions are unable to access the drug.

The first person to be prescribed medical cannabis in the UK, Carly Barton, was turned away by an NHS pharmacist because the drug had not been imported. Many other patients have since had similar experiences. So, why is a world-leading cannabis producer unable to provide its own patients with the medical cannabis they need?

Morphine is also a schedule two drug under the Misuse of Drugs Regulations 2001. However, unlike cannabis, it has a well-established medical use, so processes are in place to import and regulate it. In contrast, importers of medical cannabis in the UK must apply to the Home Office for a license and the process can take up to 28 days, by which time a patient's prescription may have expired. Bulk imports of medical cannabis may be necessary to meet demand.



To improve access to medical cannabis, the negative stigma associated with the drug must be dispelled. It is important that decision-makers realise the therapeutic potential that medical cannabis offers and are aware of the currently unmet need in the healthcare industry. There are two important ways to change minds – effective scientific communication and further research.

### **Scientific communication**

In 2016, Billy Caldwell, a young boy with severe epilepsy, began taking medical cannabis in the U.S. His condition improved dramatically from approximately 100 seizures a day to 300 days with no seizures at all. However, laws at the time meant Billy could not take medical cannabis in the UK, so his mother Charlotte Caldwell began campaigning for change.

Charlotte regularly appeared in the media to share Billy's story, from his prescription for medical cannabis

on the NHS in 2017 to the [Home Office](#) ordering his doctor to stop the prescription in June 2018 and the confiscation of Billy's medication at Heathrow Airport. Charlotte and Billy's campaign rapidly gained support from the media and the public, which led Home Secretary Sajid Javid to intervene with arguably the biggest reform of UK drug laws in recent times – the legalisation of medical cannabis. This result demonstrates the positive impact that communication can have when it reaches key decision makers.

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**“To improve access to medical cannabis,  
the negative stigma associated with the drug  
must be dispelled.”**

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It is important that we continue to talk about stories like that of the Caldwell family, to increase awareness among decision makers of the scale of the issue and how it can be resolved. There are several societies,



non-governmental organisations (NGOs) and patient advocacy groups already helping to facilitate these conversions.

For example, last year, the Royal College of Physicians declared that it is in favour of decriminalising cannabis use.

Also, the British Medical Journal announced that it “is firmly behind efforts to legalise, regulate and tax the sale of drugs for recreational and medical use. This is an issue on which doctors can and should make their voices heard.”

A key target of our communication strategies should be UK doctors, many of whom may not be prescribing medical cannabis to patients who need it, due to a lack of knowledge and experience. Medical students should be taught about the endocannabinoid system, the biological system that CBD acts on, and should also be kept informed on the latest clinical research into the use of medical cannabis to treat a range of conditions.

### **Collect more data**

Existing data to support the use of CBD in healthcare is mainly in the form of reports, observational studies, and surveys. These methods rely on self-reporting from patients, do not use control groups and do not use standardised strains of the drug. Therefore, they cannot be used as part of the formal regulatory approval process that a drug must go through for it to become a licensed medication. Thorough data from randomised clinical trials on the efficacy and safety of medical cannabis is required for the healthcare industry to increase its confidence in the drug and license it for a greater number of patients.

Scientific research could also help to improve the medical cannabis supply issues that the UK currently faces. In Canada, a collaboration between cannabis production company RavenQuest Biomed and McGill University in Montreal is investigating how changing growing conditions of the cannabis plant can be used to manipulate the cannabinoid profile for cannabis-derived medicines.

Rachel Backer, a postdoctoral fellow at McGill University said: “We are looking into three beneficial bacteria that have the potential to alter the cannabinoid profiles of the cannabis plant.

“Cannabinoids are synthesised by the plant to moderate stress and these bacteria are able to induce stress responses in plants, without the actual stress being present.

“By applying the beneficial bacteria, there are two things we hope to achieve,” Backer continued. “First of all, we believe we can increase the yield of the plant, which would help increase the supply of cannabis for medicinal use.

“Secondly, we believe that applying the beneficial bacteria will alter cannabinoid expression by the plants. We can use this to understand what controls the expression of the molecules responsible for the therapeutic effects of cannabis, such as CBD. In the future, we may be able to modify the cannabinoid profile of plants to allow for targeted treatment of a variety of medical conditions.”

Cannabis has the potential to transform lives and considerably improve healthcare services in the UK, but negative associations with the drug are hindering its progress. With effective communication and reliable data, we can change minds about cannabis and trigger further reforms so that people like Billy Caldwell and Carly Barton can live happier healthier lives. ■

**Ramya Sriram**  
**Digital Content Manager**

Kolabtree  
contact@kolabtree.com,  
www.kolabtree.com/  
www.twitter.com/kolabtree

# The future for hemp: What is at stake?

Lorenza Romanese, Managing Director of the European Industrial Hemp Association (EIHA) examines the future of hemp and explains in this vein, what is at stake, as well as looking back at its fascinating history

**H**emp has provided essential raw materials and a high protein and health-promoting food source for centuries, more likely millennia. The hemp plant has been used for construction, paper, textiles, ropes and other applications contributing significantly to the advance in western civilisation. Hemp was grown in Europe and most countries worldwide until the 1930s, after which cultivation got almost eradicated.

Since the end of the 20th century, hemp is making a comeback and is emerging as one of the most rapidly growing agricultural and industrial markets that have emerged for decades.

To clarify, we are talking about “hemp” (*Cannabis sativa* L.), which is authorised under the EU’s [Common Catalogue of Varieties of Agricultural Plant species](#) (Reg. 1308/2013) and contains less than 0,2% of THC, which means it is not psychoactive.

The world is facing enormous challenges – how can we transition from high carbon to a low carbon economy? To achieve this, hemp has a valuable contribution to play and offers economically viable solutions to help address some of the major challenges our societies currently face, including pollution, carbon emissions,

plastics waste, world hunger, people’s health, lack of jobs and rural underdevelopment.

## What are the key benefits of hemp?

The production of Hemp is *carbon negative*, which means it absorbs more carbon from the atmosphere during its growth than is emitted by the equipment used to harvest, process and transport it.

It is 10,000+ environmentally responsible industrial and consumer applications including bioplastics, composites, construction materials, high protein foods and beverages, health-promoting food supplements, textiles, paper products, biofuel, graphene substitutes.

It gives major environmental benefits. Significant carbon sequestration, enhanced biodiversity and a late season food source for bees, land reclamation and phytoremediation.

Also, hemp can be a profitable cash crop for farmers when permitted to utilise the whole plant.

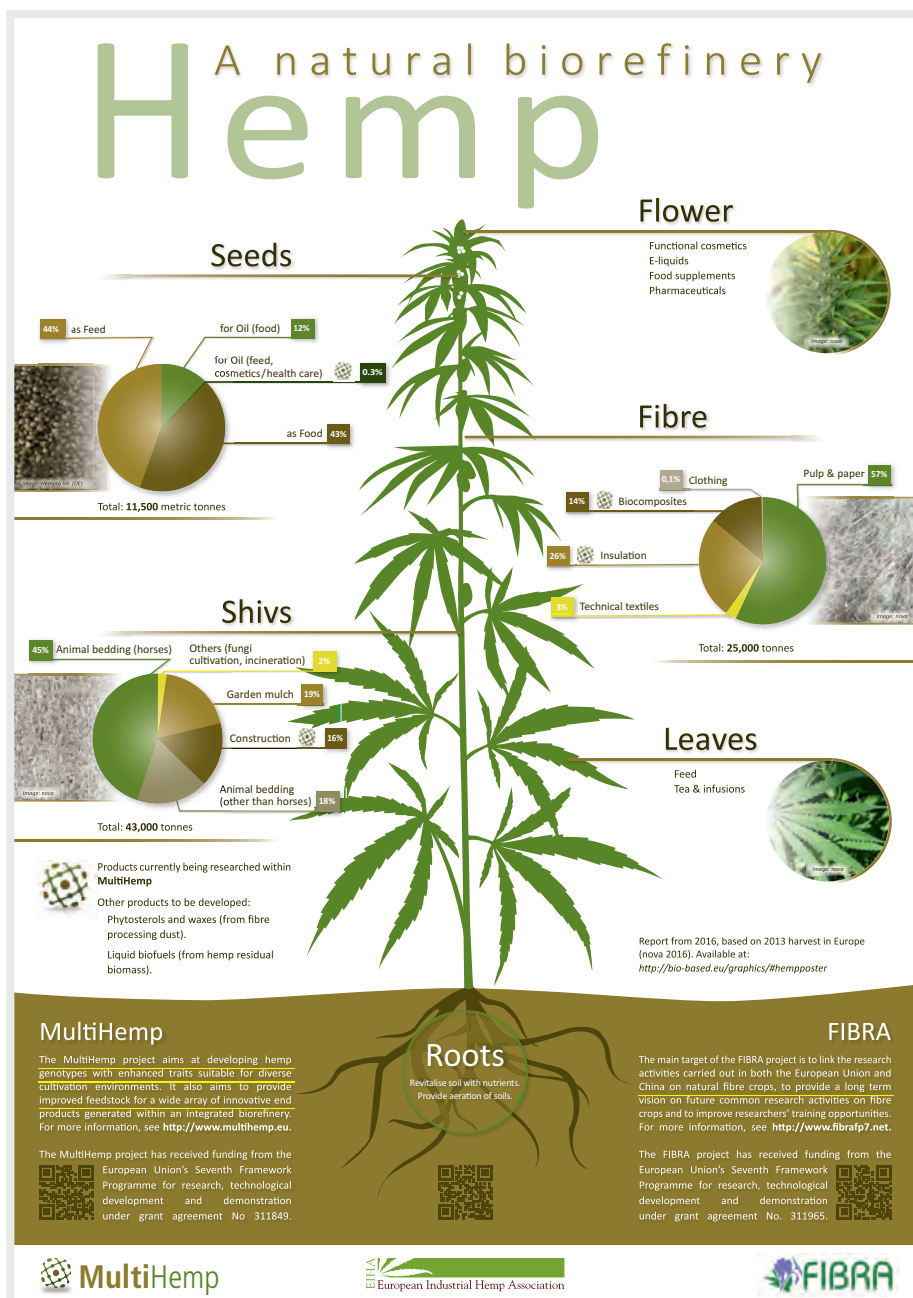
## What are the barriers to growth?

Almost 60 years ago, the hemp plant, which was widely used as food for centuries, was erroneously designated alongside the cannabis (marijuana)

flower as a narcotic substance in the UN Single Convention. This has caused a lot of confusion as cultivation of cannabis plants for industrial purposes is clearly exempted from the scope of international control because the industrial hemp sector has been severely restricted in terms of onerous licensing procedures and unclear and complex European and national regulations dealing with hemp-derived food products.

Hemp foods and drinks from flowers leaves and extracts re-emerged in the 1990s. In response to the introduction of the Novel Food catalogue in 1997, the hemp industry collated data about the volume of sales and product types which use hemp flowers and leaves and submitted it as requested. In 1998, the hemp industry received written confirmation from the EU (PAFF Standing Committee) that: “it was decided that foods containing parts of the hemp plant do not fall under the EU Regulation EC258/97 on Novel Foods and Novel Food ingredients.” The second letter from PAFF confirmed hemp flowers and leaves are food ingredients.

Hemp naturally, abundantly contains cannabinoids, is best known as cannabidiol (CBD). In the 21st century, awareness is rapidly increasing that consuming healthy foods and supplements can be an important



supplements prompted the PAFF committee to revisit the permitted consumption of hemp products and on 20th January 2019, the same committee that previously acknowledged in writing to the hemp industry 20 years earlier, that hemp flowers and leaves is a food now changed their minds and changed the Novel Food catalogue only permitting seeds for food use. Overnight the legitimate hemp foods industry was declared novel, meaning there is no history of consumption prior to May 1997.

In response, EIHA has prepared pieces of strong, extensive evidence that hemp cannabinoids/CBD have been consumed in Europe for centuries (insert a link to the evidence). One of the oldest cookbooks in the world, De Honesta et Voluptate (1475) lists a recipe on how to make modern-day CBD oil, medieval monks ate hemp soup, an Italian recipe (1887) shows how to make hemp flower tortellini, a Polish cookbook lists hemp as a vegetable, the Maltos-Cannabis Hemp Extract drink won a prize at the World Exhibition in Antwerp in 1894 and more. This evidence clearly shows that it is disingenuous to argue that leaves and flowers in food are novel today.

factor for our overall health and wellbeing. This prompted the introduction of hemp extracts in food supplements, commonly known as CBD oils. The reason hemp foods is so important to our health is that all humans and vertebrates have an important physiological system, the endocannabinoid system (ECS). The ECS fulfils a vital role and aids homeostasis. Whilst our body produces its own, so-called endocannabinoids, this is not necessarily sufficient and we can maintain and support this

important physiological system by consuming phytocannabinoids, as we used to do for millennia.

**Hemp flowers, leaves and extracts are a traditional food**

Historical records show that naturally rich in CBD/cannabinoids hemp oils, flowers, leaves and hemp extracts were widely consumed. It was an integral part of our European diet.

During the last three years, the popularity of CBD containing food







Hemp field

## Why is the use of the hemp flower and leaves so important for the entire hemp industry?

The hemp flower and the leaves are the most profitable part of the plant. If the hemp sector is only allowed to use the seeds and stalks, alongside onerous licensing procedures, this is simply not sufficiently financially viable and undermines investment into R&D and the development of large-scale, next generation, environmentally responsible industrial and consumer products. The recent rewording of the Novel Food catalogue, therefore, threatens the entire European hemp industry as the process is expensive and a novel food application takes several years to assess.

Due to the fact that the hemp industry received written confirmation from the EU (PAFF Standing Committee) in 1998 that hemp flowers/leaves are permitted for food use and the hemp industry can provide ample and substantial evidence that naturally

occurring CBD has been in the human food chain for millennia, we request that our extensive evidence is considered and that the novel food catalogue is reworded, permitting hemp foods containing cannabinoids/CBD up to levels that are naturally present in the plant (which was the status in 2018). This means that CBD containing food supplements contain no more than we would naturally consume if eating traditional hemp foods.

## So, what is at stake?

**The Hemp plant is capable of helping to solve some of the core issues we face:**

- Foods and supplements (seeds/flowers/leaves) maintain and support our health.
- The stalk provides zero carbon raw materials ideal for the next generation of environmentally responsible applications, helping mitigate the environmental emergency.
- The hemp industry has a real opportunity to play a leading role in the development and expansion of a low carbon, environmentally responsible industry, bringing a new 'cash-crop' to European agriculture and creating jobs across the entire supply chain.
- For hemp to be a viable cash crop for our farmers and processors, they need to be empowered to utilise the whole plant.
- EIHA and its members offer our extensive knowledge and expertise to help establish a framework permitting the use of the whole plant that satisfies both regulatory agencies and industry.

*"CBD has been found to be generally well tolerated with a good safety profile." Excerpts from a letter of WHO Director General to Secretary-General of the United Nations, July 23, 2018*

*"The Science Museum's three-storey building is constructed using a hemp-lime envelope and was so effective that they switched off all heating, cooling and humidity control for over a year, maintaining steadier conditions than in their traditionally equipped stores, reducing emissions while saving a huge amount of energy." Dr Mike Lawrence is Director of the University of Bath's new research facility, the Building Research Park*

*"It has been calculated that the serial implementation of the lightweight biomaterials on the high-volume vehicles will deliver a reduction of 40,000 tons of CO<sub>2</sub> emissions and the ability to drive an additional 325 million kilometres with the same quantity of fuel." Source: Autocar Pro Newsdesk 3/2018.*



**Lorenza Romanese**  
**Managing Director**  
 European Industrial Hemp Association (EIHA)  
[lorenza.romanese@eiha.org](mailto:lorenza.romanese@eiha.org)  
[www.eiha.org](http://www.eiha.org)  
[www.twitter.com/EIHA16](https://twitter.com/EIHA16)



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# CBD: A brief introduction to a brand-new industry

Mile High Labs International Limited provides a brief introduction to a brand new industry, CBD, a non-psychoactive cannabinoid

The United States (U.S.) is in the midst of a hemp revolution, thanks in part to last year's Agricultural Improvement Act of 2018 (commonly known as the 2018 Farm Bill) that paved the way for legal production. Today, across the U.S., hemp is grown to produce CBD, a non-psychoactive cannabinoid that has become one of the most talked about and least understood ingredients in the marketplace.

Recently, the U.S. Food and Drug Administration held a public hearing to determine a pathway toward regulating CBD and was struggling to bring its regulatory framework to where it needs to be, in the wake of a massive increase in sales. In the United Kingdom, while we are somewhat earlier in the rapidly growing market (where sales are projected to be worth some \$22 billion within three years), CBD sales have reached over 250,000 consumers in the UK, double the figure for the previous year.

It appears that CBD is everywhere. In America, the CBD industry is booming and in Europe, there are more questions than answers. What is CBD? How can you be sure it's safe? What does a European CBD market look like?

## Who is Mile High Labs?

Mile High Labs is an industrial-scale CBD ingredient manufacturer offering a reliable delivery of bulk CBD

(and private labelling services to the world's leading consumer brands). With a GMP certified extraction facility and an extensive network of contracted cultivators, Mile High Labs supplies high-quality, high-volume CBD orders year round.

**"By educating our customers and upholding the highest standards for our products, Mile High Labs intends to become the trusted leader in the marketplace on both sides of the Atlantic."**

Mile High Labs is headquartered in Boulder, Colorado and operates offices and distribution centres in the U.S. and Europe. From a European perspective, there may be misunderstandings around the company brand name. The name Mile High Labs is derived from the fact that Denver is known as the "Mile High City" as it is exactly 5,280 feet above sea level. The city's American football team plays at Mile High Stadium and throughout the state, there is everything from auto dealerships to churches with "mile high" in their name.

## What is CBD?

CBD is short for cannabidiol and is extracted from industrial hemp. It is a cousin of the Marijuana plant. Although they look similar, their properties are very different. Simply put, CBD doesn't get you high.

The hemp is harvested and processed

to extract the cannabinoids, of which CBD is one of many. At Mile High Labs, we refine the CBD one step further by separating it from the other cannabinoids. This finished product is "isolate," a white, almost odourless and flavourless powder that resembles cornflour or icing sugar and is greater than 98% pure CBD.

Because we are isolating the CBD molecule, our product contains no THC. It's compliant, safe and highly versatile. We can qualify its purity and cannabinoid content, allowing us to confidently ship it to open markets across the world.

## New technology for better safety

CBD isolate is a significantly refined, highly concentrated premium product. To ensure the safety of the product, Mile High Labs uses blockchain technology to track the isolate from field to sale. The blockchain creates a digital paper trail of every human interaction with the product. The resulting data is unalterable and serves as the isolate's pedigree.

"Blockchain technology helps us aggregate data from all of the systems within our supply chain to ensure no information gets lost or altered as the product moves from farm to lab and ultimately into the hands of the customer," says Sébastien Pasquali, Head of Information Technology at Mile High Labs.





Not only does blockchain technology help ensure quality for customers but it also helps CBD companies self-regulate in an underregulated market.

**“Because we are isolating the CBD molecule, our product contains no THC. It’s compliant, safe and highly versatile. We can qualify its purity and cannabinoid content, allowing us to confidently ship it to open markets across the world.”**

While the 2018 Farm Bill created a path towards legal hemp production, there were few measures put in place to regulate products derived from hemp. While further updates from the U.S. Food and Drug Administration are expected over the summer, Mile High Labs continues to implement quality assurance and control processes drawn from the pharmaceutical industry.

### **CBD in Europe and the UK**

As CBD products become more prevalent in Europe and the UK, the Centre for Medicinal Cannabis (CMC) is leading the discussion on regulation and research. Mile High Labs is working alongside CMC to educate stakeholders and the public about CBD and develop a roadmap for strong regulations.

“We’re building global trust in CBD as an effective and safe ingredient,” said John Wallace, Managing Director of UK/EU for Mile High Labs. “Not only customer and consumer trust, but the trust of the regulatory officials that oversee the import and export of CBD ingredients and products.”

By educating our customers and upholding the highest standards for our products, Mile High Labs intends to become the trusted leader in the marketplace on both sides of the Atlantic.

You can learn more about our company and the industry by visiting [milehighlabs.com](https://milehighlabs.com) or contacting Mile High Labs International Limited at [info@milehighlabs.co.uk](mailto:info@milehighlabs.co.uk) or +44 (0)28 9099 5253.



Mile High Labs International Limited  
Tel: +44 (0)28 9099 5253  
[hello@milehighlabs.co.uk](mailto:hello@milehighlabs.co.uk)  
[www.milehighlabs.com](https://www.milehighlabs.com)

# An overview of medicinal cannabis research

Dr Mark Ware, Chief Medical Officer at Canopy Growth, provides an overview of the research that already exists around medicinal cannabis and explains why there is a need to educate clinicians further

The medicinal cannabis industry is growing rapidly in the UK with new and established companies entering the market, all aiming to supply patients with new formulations of otherwise old medicine. However, despite regulations allowing for legal use of medicinal cannabis on November 1st, 2018, very few patients are able to access these medicines either privately or on the NHS.

There have been a small number of patients championing access to medicinal cannabis, such as Billy Caldwell and Alfie Dingley, both of whom are among the very few who have managed to obtain a prescription in the UK as of the time of writing.

One factor contributing to the shortage of prescriptions to date is lack of educational support given to clinicians; another is the shortage of clinical evidence supporting the efficacy of different kinds of cannabinoid preparation. As medical training in this area is not standard for clinicians, many are having to do their own research to learn more about the potential safety and efficacy of cannabis.

Additionally, some hospitals have banned the prescription of medicinal cannabis and others have asked for reassurance that their jobs will not be at risk if they prescribe.

While there is a clear case for further research, cannabis and its components have been extensively investigated and used as a medicine for many years, with evolving clinical and real-world evidence suggesting the potential benefit of cannabinoids for those with Multiple sclerosis (MS), chronic pain, cancer treatment-related nausea and epilepsy, among others. However, this evidence is not widely shared or appreciated in undergraduate or continuing medical education for health professionals.

## Chronic pain

Relief from chronic pain associated with cancer, musculoskeletal disorders and central and peripheral neuropathies is among the most common reasons cited by patients for the medical use of cannabis. <sup>(1)</sup> However, clinical trial data are suggestive, but not conclusive, of cannabis treatment of chronic pain. <sup>(2)</sup> Issues include lack of standardised products, heterogeneity of conditions, small sample sizes and short follow up. Neuropathic pain appears to be the most well-studied condition. Overall evidence suggests that cannabinoids deserve consideration as a treatment option for refractory pain, with increasing calls for cannabinoids to be evaluated as alternatives to opioids. <sup>(3)</sup>

While a large number of studies suggest cannabinoids can have a moderate effect on pain, more research needs to be done in regard to efficacy, dose, routes of administration and safety.

## Epilepsy

A number of recent reviews have shown that cannabidiol (CBD) is more effective than placebo in reducing the number of seizures by 50% or more and improved overall quality of life. <sup>(4)</sup> Indeed, the U.S. FDA recently approved a prescription form of CBD for refractory childhood epilepsy conditions.

## Multiple sclerosis (MS)

Spasticity and pain in MS have been well studied as targets for cannabinoid therapy and in a review of 17 studies, use of cannabis-based products have been found to be associated with improved patient-reported spasticity in the long term. <sup>(5)</sup>

## Addiction

A 2016 survey of consumers attending a Michigan medical marijuana dispensary suggesting that medical



cannabis use in pain patients was associated with a 64% reduction in opioid use. <sup>(6)</sup> Likewise, analyses of prescription data from U.S. Medicare enrollees in the U.S. (with medical access to cannabis) suggest that access to cannabis is associated with a significant reduction in the prescription of conventional pain and other medication. <sup>(7)</sup> In the context of an evolving crisis of mortality associated with opioid abuse, the role of cannabis in reducing harms associated with substance abuse deserves urgent consideration.

### Adverse effects

Cannabis products are generally well tolerated, however common side effects for CBD or high THC (tetrahydrocannabinol) products include nausea, vomiting, diarrhoea, fatigue and dizziness. <sup>(8)</sup> The role of cannabis in patients with mental health disorders deserves careful study.

Dr Ware finishes: "Overall, cannabis may have benefit to very ill patients who are refractory to conventional therapy. More research into the efficacy and side effects of a variety of cannabinoids is clearly needed. However, there are many patients in the UK who cannot and will not wait for further clinical research and these patients deserve and need their clinicians to feel confident enough to prescribe cannabis. With better information and guidance, clinicians and patients can work together to evaluate whether cannabis may be appropriate for them." ■

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### Dr Mark Ware Chief Medical Officer

Canopy Growth

Tel: +1 855 558 9333

[www.canopygrowth.com](http://www.canopygrowth.com)

[www.twitter.com/CanopyGrowth](https://www.twitter.com/CanopyGrowth)



# Europe setting standards for cannabis products

As government authorities come to grips with legislation of cannabis-based products, the European market holds a key position, Liam McGreevy, CEO, Ethnopharm Ltd explains

As government authorities come to grips with legislation of cannabis-based products, expanding rapidly year on year, the European market holds a key position.

The combination of population, GDP, nationalised healthcare, and cultural historic use in many countries makes Europe an attractive market for global producers of cannabis-based products, both medical and retail.

European standards are, therefore, now the benchmark to be achieved to facilitate market entry, and Europe has an opportunity to lead the way in establishing sensible regulatory systems that provide safe access to appropriate products while not unnecessarily burdening what have been historically widely consumed products.

## The CBD explosion

Europe was the seat of the explosion of the now global CBD trend. While North America progressed medical cannabis legislation across its states over the last fifteen years, these have been high THC focused products based on modern indoor grown plant varieties. CBD was considered a scheduled substance and the cultivation of hemp was banned in the U.S. until this year, leaving a severe lack of high CBD genetics.

Brands like Endoca and Enecta were some of the first to establish a presence using online sales and social

media channels to raise consumer awareness of the potential benefits of CBD, and they were particularly successful in countries like UK, Italy and Greece.

European Union (EU) national regulators have struggled to get to grips with the regulation of cannabidiol products, which has proven difficult given that CBD is not a scheduled controlled substance, hemp food products were historically consumed, and extracts of the plant were manipulated for use in medicines and many other applications.

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**“The idea that an extraction process providing a concentrated form of a plant, which is then formulated into products in low strength, is somehow novel when it is standard practice for a plethora of food products is a strange position to take.”**

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## The science

While parties who claim there isn't sufficient evidence for the medical efficacy of cannabidiol have a point, there is actually a wide base of early stage studies exploring its effects, the physiological systems it impacts, and the mechanisms behind the benefits so many consumers experience.

Cannabidiol doesn't get you high, it mostly doesn't interact with the main cannabinoid receptors, it interacts with a range of g-coupled protein receptors and particularly interesting is its interaction with the anandamide receptors.

These exist in the walls of almost every cell in our bodies, triggering our response in fight or flight stress situations, managing vasodilation and heart rate. CBD's impact on anxiety and stress may be legitimate, it may not all be placebo after all. Cannabinoids and terpenes are powerful compounds whose synergistic effect we are only beginning to comprehend.

With a decade of austerity under our belt, and the progression of automation in the workforce and our daily lives, it should be no surprise that stress and anxiety are becoming more prevalent. One thing that seems to be clear from several studies, as well as the clinical trial testing on Epidiolex, is that CBD is well tolerated and very safe in low daily doses. Given so many consumers are willing to spend their hard-earned money on these products, there is something genuine underlying this technology, and EU companies should have the opportunity to lead this emerging technological field.

## The rocky road to a regulated market

Given the widespread and often confusing information being distributed online by companies and brands exploiting a new market area, health authorities are right to protect consumers from false advertising and medical claims, particularly considering that an ICCI market review tested sixty CBD products and found thirty (50%) of them to contain contaminants.



The UK health authority Medicines and Healthcare products Regulatory Agency (MHRA) attempted to protect consumers by classifying CBD as a medical product following the approval of Epidiolex, to restrict medical claims. This had little impact however, with brands and retailers simply tweaking their materials to suit the new parameters....and still many products are on the market today that contain contaminants, or whose contents are nothing like that described on the label.

The recent EFSA guidance note is interesting in that it attempts to provide some clarity between a traditional hemp food product and a 'new' or novel concentrated plant extract. Unfortunately, this has only left confusion across many EU markets, with good operators not sure how their national FSA will decide to regulate.

The idea that an extraction process providing a concentrated form of a plant, which is then formulated into products in low strength, is somehow novel when it is standard practice for a plethora of food products is a strange position to take.

**"The combination of population, GDP, nationalised healthcare, and cultural historic use in many countries makes Europe an attractive market for global producers of cannabis-based products, both medical and retail."**

## Building safe markets

So, the regulatory path to date hasn't been smooth, and in actual fact it hasn't worked in making the market safer for those who wish to use CBD products where they feel they offer benefits. If anything, the current regulatory pathway of trying to close the

market down only pushes consumers further into the grey market.

What European consumers need is a range of safe strength CBD products available in their normal retail environments, grown, extracted, manufactured and labelled to safe European standards.

## ETHNOPHARM

**Liam McGreevy**  
**CEO**

Ethnopharm Ltd  
Tel: +44 (0)773 865 8223  
liam@ethnopharmgroup.com  
www.ethnopharmgroup.com

# Medical cannabis vaporizers

Vatra Sylva, Head of Marketing, Storz & Bickel GmbH & Co. KG, discusses the importance of medical cannabis vaporizers

Cannabis has gained an increasing importance in the medical field in the past years with more and more countries recognising its medicinal value. While medical cannabis products come in different forms and variations – like extracts, tinctures, gel capsules, sprays etc. – the cannabis flower is still an integral part of the cannabinoid therapy and is ultimately the cannabis product which raises the most questions when it comes to the correct administration.

The German-based Storz & Bickel GmbH & Co. KG is the first manufacturer of medical cannabis vaporizers worldwide and specialised in providing reliable and medically certified vaporizers and with that, a validated method for cannabis inhalation.

## Cannabis administration

Depending on the cannabis product, different administration methods have been suggested. Extracts and gel capsules, for example, are substances in which active cannabinoids are dissolved in a suitable liquid, primarily for oral intake. The cannabis flower is different in the way that cannabinoids are present in the plant as non-effective acids, which must first be activated by decarboxylation through heat exposure. One way to achieve this is by consuming cannabis as an ingredient in baked goods or teas.

The oral administration of cannabis flowers is occasionally still proposed as a means of intake by some health-



care professionals and doctors, although it does not represent an optimal medical administration method due to the lack of validated recipes to which patients could be directed.

Furthermore, when cannabis is administered orally, the (self-) dosage is aggravated as the onset of effect can take up to 90 minutes and can last for 4-6 hours depending on the patient's weight, metabolism and whether the patient has eaten before or not. Another unpredictability linked to the oral administration of cannabinoids is that inexperienced patients may not notice the effect of the initial administration right away and might, therefore, increase the dose too early.

## Cannabis inhalation

The most popular way to consume cannabis flowers is via inhalation; In

comparison to oral intake this has a much more rapid onset of effect because the active ingredients enter the bloodstream through the alveoli in the lungs relatively quickly. The effect is usually felt within 1-5 minutes and lasts for approximately 2-3 hours. For many patients with acute ailments this type of administration therefore offers a clear advantage over the oral administration. It is also easier for patients to find the right dosage because of the quick onset of effect.

There are two possibilities for inhaling cannabis. A widely used inhalation method is smoking. For most patients, this is the simplest and most convenient method because no special device is required. The disadvantage of this method is the inhalation of toxins that are generated when the dried flowers are burned. Toxic





combustion substances such as polycyclic aromatic hydrocarbons (PAH's), ammonia, and carbon monoxide (can) adversely affect the health of patients. This method is therefore not acceptable for medical use, especially when combustion-free cannabis vaporizers offer an alternative to smoking.

## Cannabis vaporization

Cannabis vaporizers are designed to heat and thereby decarboxylate the cannabinoids in the flower in a controlled manner and to convert them into an inhalable aerosol without creating any toxic byproducts.

In the past years, a whole industry has evolved around cannabis vaporization and the market has been flooded by vaporizers of different shapes, sizes and built qualities. When considering vaporization as a means of medical cannabis administration however, great significance should be assigned to the functionality, quality and reliability of these devices to ensure their efficiency and patient safety.

ISO 13485 certified manufacturer Storz & Bickel offers two medical cannabis vaporizers, the VOLCANO



MEDIC and the MIGHTY MEDIC. The vaporizers are developed and manufactured in Tuttlingen, Germany according to the European Medical Device Directive 93/42/ECC and Standard DIN EN 60601. Both devices are currently approved in Europe, Canada and Israel with more medical cannabis markets to be added in the future. The VOLCANO has been used in cannabis research worldwide for more than 15 years and is the vaporizer with the most validation from the scientific community.

Both devices use a controlled heating technology and offer the possibility to precisely adjust the heating temperature via the display on the device, which gives the user full control over the density of the produced aerosol. This can be valuable for inexperienced users, who are hereby able to start vaporizing at lower temperatures to produce a light vapor for a more pleasant inhalation experience. The maximum temperature that can be reached by the devices is 210°C. Validation studies have shown that at this temperature, THCA (TetraHydro-Cannabinolic Acid, Cannabidiolic Acid (CBDA), and the terpenes are almost completely dissipated without combustion taking place. If used according to the manufacturer's instructions, the systemic bio-availability of vaporized cannabinoids from cannabis flowers

with the VOLCANO MEDIC and the MIGHTY MEDIC is 29-35%. In comparison, the systemic bio-availability of orally absorbed cannabinoids has been reported to be below 15% due to the first pass effect in the liver.

## The importance of cannabis vaporizers for medical professionals and patients

Medical cannabis vaporizers should be part of any discussion involving cannabis (flower) therapy. Other administration forms of cannabis have proven to be either harmful due to the production of toxic byproducts, or suboptimal due to the lack of validation data. Looking forward, it is of utmost importance that healthcare professionals are informed and sensitized to prescribing the correct cannabis administration form for their patients.

Furthermore, authorities should be responsible for ensuring that safe cannabis delivery methods are available to patients, ideally by including them into a reimbursement or insurance coverage plan to help prevent patients from relying on unhealthy cannabis intake methods.



**STORZ & BICKEL**

**Vatra Sylva**

**Head of Marketing**

Storz & Bickel GmbH & Co. KG

Tel: +49 7461-969707-0

info@storz-bickel.com

www.storz-bickel.com



# Japan: Challenges around global data sharing for orphan diseases

Makoto Suematsu, President of the Japan Agency for Medical Research and Development (AMED) details the challenges around global data sharing for orphan diseases

Japan Agency for Medical Research and Development (AMED) was launched in April 2015 under the robust initiative of Prime Minister Shinzo Abe and the Cabinet Secretariat in Japan to fast-track medical research and development (R&D). Among the nine pillars of medical research fields in AMED, those in which we are changing for global data sharing today are rare diseases and human genetics and infectious disease research. In these research areas, data sharing among different countries is indispensable for saving the lives of patients and communities.

When it comes to rare and undiagnosed diseases, data sharing plays a vital role in ensuring a correct diagnosis for patients. There are generally two categories of patients who suffer from diagnostic odyssey under undiagnosed states: 1) Unknown and ultra-rare diseases that are not mentioned in any articles or textbook and; 2) Known diseases (including what many countries designate as intractable diseases and conditions only known for their syndrome names), which are so difficult to detect that patients remain largely undiagnosed. From the viewpoint of undiagnosed patients,

however, the two categories are practically the same. With intractable diseases, very few definitive treatments have been established, so physicians working in isolation have little chance of preventing the deterioration of symptoms or of mitigating patients' pain, therefore, cooperation with patient support groups, pharmaceutical companies and those in diverse other fields is essential.

Of particular importance is data sharing across national borders. To deal with rare and undiagnosed diseases, it is critical to empower international cooperation to build data and knowledge bases to get as much patient data as possible registered. It is also necessary to constantly accumulate and update data on patients' age, symptoms, pathogenic gene variants and addresses to contact physicians who take care of patients and families. Such efforts not only help speed up diagnosis but also provide valuable information to pharmaceutical companies developing cures and the fruit of their research can be delivered more quickly to patients. Based on the premise that all patients have the right to participate in clinical research and trials, the present authors believe a data sharing platform must be established that will help researchers analyse patients' data from multiple perspectives, including those of science, bioethics, R&D feasibility and pain mitigation (which is the primary concern of patients). The collected data should facilitate and reinforce R&D efforts by cooperating pharmaceutical companies and ventures.

Undiagnosed Disease Program (UDP) was first started in NIH Hospital by Dr William Gahl, who has expanded the idea to UDP-International. Japan has a half-century history of rare disease (NANBYO) researchers but a domestic network never existed. AMED launched Initiative on Rare and Undiagnosed Diseases (IRUD) during October 2015. From the start, AMED aims to build up a data-sharing network which covers Japan and today, consists of 438 hospitals that includes not only major university hospitals but regional core children's hospitals.

To accelerate accumulation phenotypic information, together with gene variant data into the data and

knowledge base, IRUD Exchange, AMED made contracts with institutes in which researchers with accepted proposals belong to, so as to share a policy of "no share, no budget." Besides publication lists, AMED is now checking track records which show how individual researchers and their groups contribute to submitting the data necessary for precise diagnosis to IRUD Exchange and those indicating the number of rare disease patients whom the diagnosis was provided for. As a result of efforts paid by all IRUD participants, more than 10,000 rare disease patients' data were stored in IRUD Exchange and now available in Matchmaker Exchange, which includes U.S., Europe and Australian data but not Asian data before us.

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**"Japan Agency for Medical Research and Development (AMED) was launched in April 2015 under the robust initiative of Prime Minister Shinzo Abe and the Cabinet Secretariat in Japan to fast-track medical research and development (R&D). Among the nine pillars of medical research fields in AMED, those in which we are competing for global data sharing today are rare diseases and human genetics and infectious disease research."**

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The four principles of bioethics (respect for autonomy, non-maleficence, beneficence and justice) must be duly observed and comparable weight should be given to the protection of privacy. Under given conditions, however, global data sharing in order to find out new patients, as many as possible over the world, is the first step to establish a global registry system for patients with orphan diseases which I dream of. ■

#### **Makoto Suematsu, M.D., PhD**

##### **President**

Japan Agency for Medical Research and Development (AMED)

Tel: +81 3 6870 2200

[contact@amed.go.jp](mailto:contact@amed.go.jp)

[www.amed.go.jp](http://www.amed.go.jp)



# A look at the Hong Kong Elderly Health Service

With a growing elderly population – and with it, a growing number of carers – Hong Kong's Elderly Health Service has an increasingly important role in promoting both good physical and mental health, as this article reveals

**H**ong Kong's Elderly Health Service was established in 1998 to oversee primary healthcare for the older population, improve their ability to self-care, encourage healthy living and strengthen family support to minimise illness and disability.

Of Hong Kong's 7.3 million population, just over 1.2 million people are aged 65 or over – and the number is rising.

The service's stated mission is to: provide client-orientated services; adopt a whole-person, multi-disciplinary team approach; develop expertise and professionalism in primary healthcare of the elderly; and to promote intersectoral collaboration and community participation.

It comprises 18 elderly health centres and 18 visiting health teams.

## Elderly Health Centres

Health centres aim to address the multiple health needs of the elderly by providing integrated primary healthcare services. They serve to identify health risks and detect diseases earlier for timely intervention and prevention of complications in a multidisciplinary approach in primary care settings.

Anyone aged 65 or over is eligible to enrol as a member of an Elderly Health Centre. As enrolled members, they are provided with services including health assessment, counselling, health education and curative treatment.

## Visiting Health Teams

Visiting Health Teams work in the community and residential care settings to provide health promotion activities for the elderly and their carers, in collaboration with other service providers.

The teams aim to increase people's health awareness, self-care ability and to enhance the quality of caregiving. All services are provided free of charge.

Visiting team services take a "train the trainer approach", meaning they are targeted at not only elderly people themselves but also carers, such as family members, home helpers, domestic helpers, staff working in residential care homes and volunteers.

The Elderly Health Service's Public Health & Administration section supports the work of elderly health centres and visiting health teams by collecting and analysing data from daily service operations to monitor the health status of Hong Kong's elderly population and inform research.

## Elderly Health Service website

The Elderly Health Service's website contains a wealth of information for elderly people and their carers on health and ageing.

Topics covered include the importance of distinguishing between changes related to normal ageing, such as hearing loss or mild shortness of breath that does not affect daily activities and other, potentially more serious symptoms that should not be ignored in order to seek early treatment for a disease.

There is also advice on getting a health check and information on some common health problems, including bone and joint issues, cancer, dementia, diabetes, hypertension and heart disease, infections, mental illness, stroke and more.

There is extensive guidance on a range of other issues that contribute to and influence health, including



maintaining good mental health, exercise, leisure and travel and healthy diet and shopping smart.

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**“Health centres aim to address the multiple health needs of the elderly by providing integrated primary healthcare services. They serve to identify health risks and detect diseases earlier for timely intervention and prevention of complications in a multidisciplinary approach in primary care settings.”**

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The website also has a dedicated section for carers covering key skills, including: lifting, transfer and proper positioning for the prevention of sores and muscle contracture; feeding the frail elderly; post-stroke care; dementia care; wound care; nutrition monitoring; and oral health.

Carers’ Corner also emphasises the importance of effective communication, which can be crucial in reducing misunderstandings, conflicts and stress and promoting good interpersonal relationships.

With Hong Kong’s population gradually ageing, the importance of maintaining healthy lifestyles in later life, early identification and treatment of disease and knowledge for carers will only continue to grow.

The Elderly Health Service’s role will be to promote not only a focus on the basic essentials of good physical health but also the broader factors that will aid the transition to retirement, staying active and maintaining good mental health. ■

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# The evolution of a unique dementia care centre in Hong Kong

Professor Timothy Kwok, Director of Jockey Club Centre for Positive Ageing lifts the lid on the development of a unique dementia care centre in Hong Kong

Care of the ever-increasing number of older people with dementia is a major challenge to most countries worldwide. Hong Kong is no exception. As the great majority of the care costs are met by families, the support for family caregivers is of paramount importance in the design of dementia care policy.

This was the primary motivation behind the collaboration between the Chinese University of Hong Kong and the Hong Kong Jockey Club in setting up of Jockey Club Centre for Positive Ageing (JCCPA) in 2000. The core service is to provide day and respite care to people with dementia. We have 76 daycare places and 17 beds on a separate floor for respite/residential care. In contrast with other residential homes, during the day, all residents under respite/residential care join in activities on the other floors for daycare.

JCCPA provides social stimulating activities and physical activities which have proven benefits to cognitive and general health of older people with dementia. As we do not receive any public funding, the centre has been run as a self-financing non-government organisation. To ensure quality service, we adopt the person-centred care approach and enforce a restraint-free environment. Our care staff are multidisciplinary and we have other visiting professionals providing more specialised services, for example,

music therapy, podiatry, family counselling, dietetic on an ad hoc basis. Recently, we have extended our service to transitional care for people with dementia who have become deconditioned by a hospital stay for acute illnesses.

One single care centre has limited social impact. That is why JCCPA has been active in dementia care research, training and public education. In research, we have demonstrated by randomised trials that family caregiver training delivered online or via telephone is effective in improving family caregiver self-efficacy,<sup>1,2</sup> calligraphy improves spatial orientation in older people with dementia,<sup>3</sup> cognitive training with or without client empowerment programme improves the cognitive function of older people with cognitive impairment (in press).

In caregiver training, we held a series of talks on dementia care which are open to family caregivers. We have built a website for family caregivers (adcarer.com) to provide information on the skill of dementia care and relaxation methods. We have held training courses for full time foreign domestic helpers.

In professional training, we started a one-year advance diploma course in dementia care four years ago. In collaboration with University of Stirling, Scotland, through more than 200 facilitators that we have trained, we have

delivered the Jockey Club Best Practice in Dementia Care programme to over 1,100 care staff in nursing homes, hospitals and day care centres. Evaluation of this training programme indicated that knowledge and attitude in dementia care has been enhanced. More importantly, the course has promoted cross-agency engagement and empowerment.

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**“Over the years, JCCPA has evolved into a unique dementia care centre which combines service, training, research and public education. Looking ahead, we shall continue to innovate in dementia care models, particularly in the application of technology in dementia care.”**

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When it comes to the education of the public on what we do, we have launched several territory-wide educational programmes to promote positive knowledge and attitude towards dementia among the general public and to establish a dementia-friendly Hong Kong. In 2010, we launched a public campaign to change the Chinese translated term of dementia which had very negative connotations. Out of over 1,300 proposed new terms, the term “brain degeneration syndrome” was chosen. This was widely reported in the public media and has been used by the media ever since. The initiative also prompted the local medical community to change the term to “cognitive impairment syndrome”. In addition, our two-year





“Jockey Club ‘Dementia Friendly Communities’ Campaign” delivered talks and workshops to over 4,000 people in public and private sectors about how to help people with dementia in their neighbourhood and workplaces. Since then, the Social and Welfare Department has launched the territory-wide dementia friend campaign.

**“JCCPA provides social stimulating activities and physical activities which have proven benefits to cognitive and general health of older people with dementia.”**

With the funding support from the Hong Kong Jockey Club, we are due to launch an online simple cognitive screening test to promote early detection of dementia. This will be followed by clinical diagnosis by trained primary care doctors and post-diagnosis

support which seeks to empower and facilitate advance care planning in family caregivers and care recipients.

Over the years, JCCPA has evolved into a unique dementia care centre which combines service, training, research and public education. Looking ahead, we shall continue to innovate in dementia care models, particularly in the application of technology in dementia care. With the expected rapid increase in demand for quality dementia care services in Hong Kong, Mainland China and South East Asia, our centre is well placed to be a regional professional training centre for dementia care.

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 賽馬會耆智園   
Jockey Club Centre for Positive Ageing

**Professor Timothy Kwok**  
**Director**

Jockey Club Centre for Positive Ageing  
(JCCPA)

Tel: +852 2636 6323

[info@jccpa.org.hk](mailto:info@jccpa.org.hk)

<https://jccpa.org.hk/>

[www.facebook.com/jccpahk](https://www.facebook.com/jccpahk)

# Preventing cancer: A whole-of-society, whole-of-government approach

World Cancer Research Fund's Policy & Public Affairs Manager, Fiona Sing, outlines what governments and society should be doing to prevent cancer and other non-communicable diseases

At [World Cancer Research Fund](#) (WCRF), we are dedicated to the prevention of cancer through diet, weight and physical activity. Around 40% of cancer cases are preventable if everyone were to have a healthy lifestyle, such as not smoking, maintaining a healthy weight, being physically active and eating a healthy diet. We analyse global research on the link between diet, nutrition, weight, physical activity, and cancer, turning the latest evidence-based research into practical, straightforward advice and information to help anyone who wants to reduce their risk of developing cancer, known as our [Cancer Prevention Recommendations](#). These recommendations are intended to be a comprehensive package of behaviours that, when taken together, promote a healthy pattern of diet and physical activity to reduce cancer risk. They are also designed to help inform policy action.

**“The prevention of cancer and other NCDs is one of the most significant public health challenges of the 21st century, requiring a whole-of-government, whole-of-society approach in response.”**

Public policy is critically important in creating environments for people and communities that are conducive to following the WCRF Cancer Prevention Recommendations. For example, what food is available and affordable and how accessible physical environments are for active ways of life are largely outside people's direct personal control. These factors are often shaped by policies beyond the health sector, such as planning and transport policies, and taxes. Governments play a pivotal role in introducing policies that create these healthier, less obesogenic environments.

That's why we created [NOURISHING](#): a framework that outlines what policy areas governments should be focusing on to encourage healthy diets and reduce



*Fiona Sing, World Cancer Research Fund's Policy & Public Affairs Manager*

overweight and obesity. Accompanying this framework is a database that gives examples of implemented policies from all over the world, including restrictions on the marketing of junk food to children, taxes on unhealthy food and beverages, food labelling, and subsidies on healthy food.

However, governments are not taking sufficient action to meet global [non-communicable disease](#) (NCD) targets. Part of the reason for this is that policymakers are increasingly facing barriers and challenges to developing and implementing evidence-informed nutrition policies that help to tackle NCDs.

At WCRF, we interviewed policy experts, advocates and academics from different countries to find out what these challenges are, creating a series of reports called [Building Momentum](#). These reports take the lessons learnt from governments who have implemented specific evidence-informed nutrition policies and collates them with the published literature to succinctly outline how to design and implement a robust nutrition policy, providing essential guidance on how to overcome common barriers and challenges in the nutrition policy process.

# The 4D'S INDUSTRY TACTICS



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The first report in the series looked at sugar-sweetened beverage (SSB) taxes and the second focused on front-of-pack food labels. The third in the series will look at restricting junk food marketing to children.

**“Public policy is critically important in creating environments for people and communities that are conducive to following the WCRF Cancer Prevention Recommendations. For example, what food is available and affordable and how accessible physical environments are for active ways of life are largely outside people’s direct personal control.”**

Common elements were identified across the reports that are important for the development and implementation of robust nutrition policies that can withstand challenges.

These challenges include a lack of public and political will, trade and legal challenges, and the influence of the food and beverage industry. We provide overarching lessons to overcome these challenges and obstacles, such as carefully considering the local context; using evidence as a foundation; setting clear policy objectives; carefully designing the policy; setting a plan

for stakeholder engagement and; including monitoring and evaluation early on in the process. And of course, being prepared for push-back from those opposed to the policy measure.

The prevention of cancer and other NCDs is one of the most significant public health challenges of the 21st century, requiring a whole-of-government, whole-of-society approach in response. Governments should prioritise prevention by introducing evidence-informed policy actions that make our environments healthier so that it is easier for people to make healthy choices. ■

**Fiona Sing**  
**Policy & Public Affairs Manager**

World Cancer Research Fund International  
Tel: +44 (0)20 7343 4200  
[international@wcrf.org](mailto:international@wcrf.org)  
[www.wcrf.org](http://www.wcrf.org)  
[www.twitter.com/wcrfint](https://twitter.com/wcrfint)



# Integrated *in vivo* imaging and mathematical modeling to investigate nanoparticle pharmacokinetics

Prashant Dogra<sup>1</sup>, Maria J. Pelaez<sup>1</sup>, Zhihui Wang<sup>1</sup>, Vittorio Cristini<sup>1</sup>

<sup>1</sup>Mathematics in Medicine Program, Houston Methodist Research Institute, Houston, TX 77030, USA

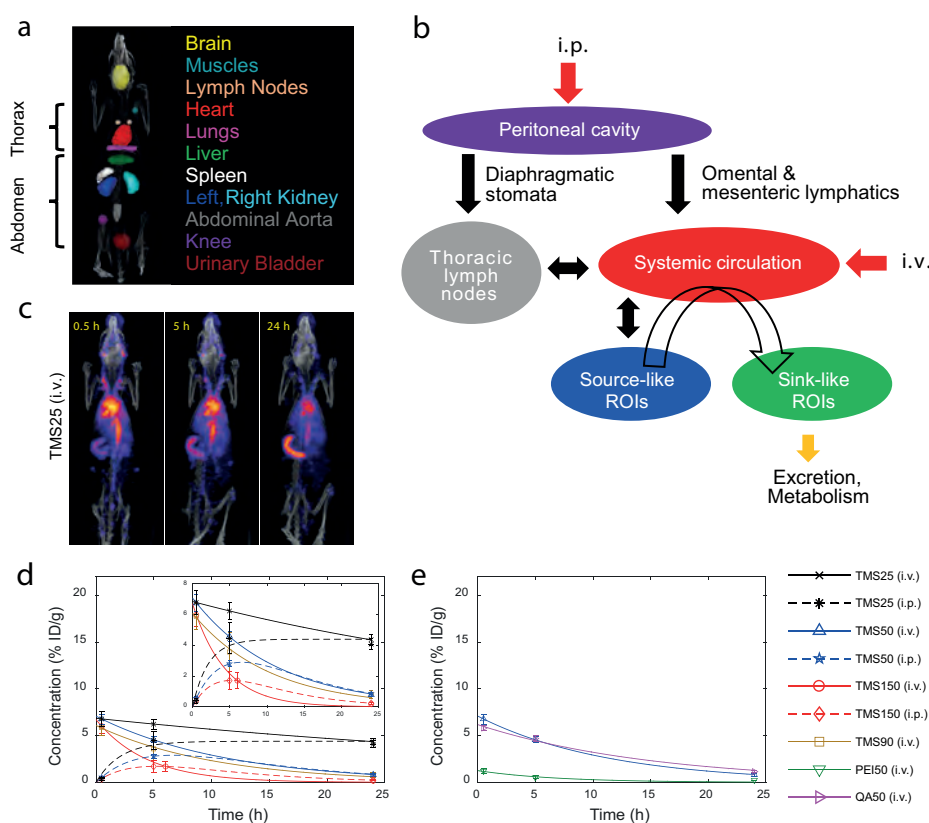
Nanocarrier-based therapeutics and diagnostics hold the promise for generating advances in drug delivery and diagnostic imaging, respectively, given their ability to carry out targeted delivery of the cargo using passive or active targeting strategies. Nevertheless, according to a review of the literature from the past 10 years, the *in vivo* nanoparticle (NP)-based delivery efficiency to tumors has averaged only around 0.7% of the injected dose<sup>1</sup>. Additionally, the clinical translation of NPs has been hindered by insufficient understanding of their *in vivo* structure activity relationships (SAR).

To establish an understanding of the SAR quantitatively, we used an integrated *in vivo* imaging and mathematical modeling approach to obtain correlations between NP physicochemical properties and their *in vivo* biodistribution and clearance kinetics<sup>2</sup>. Healthy female rats were injected with radio-labeled mesoporous silica nanoparticles (MSNs) and imaged over time using the single photon emission computational tomography/computational tomography (SPECT/CT) imaging modality. The serial images were computationally quantified to obtain radioactivity concentration (surrogate for NP concentration) in various

regions of interest (ROIs) across the body of the animal (Figure 1a). The kinetics data were used to develop a semi-mechanistic mathematical model (Figure 1b) and non-linear regression was performed to estimate important model parameters.

MSNs were selected for this study due to their high *in vivo* stability, ability to undergo surface functionalization, and precise synthesis control that allows for selection of particle size, shape, and pore size. In our investigation, MSNs were systematically varied in size, charge, and surface chemistry, in addition to their route of administration (intravenous or intraperitoneal). Three different surface chemistries for the indium (<sup>111</sup>In)-labeled MSNs were tested, (1) PEG-polyethylenimine (PEG-PEI), (2) PEG-quaternary amine (PEG-QA), and (3) PEG-trimethylsilane (PEG-TMS). All three configurations presented nominal diameters of 50 nm, and average pore diameters of 3.5-3.8nm. Further, PEG-TMS was also tested for nominal diameters of 25, 90, and 150 nm to investigate the role of particle size in disposition kinetics. Zeta potential measurements showed that PEG-TMS MSNs were neutral, while PEG-PEI and PEG-QA were strongly positively charged.

As seen in Figure 1c, the radioactivity observed in the SPECT/CT images is produced collectively by NPs circulating through the vasculature of a ROI, and by NPs sequestered in the extravascular space of the ROI. The first group of NPs are still bioavailable for delivery to the target site, while the second group is trapped at non-target sites, unless already at the target. To mechanistically describe the generalized biodistribution of MSNs, the ROIs were classified into 'sink-like' and 'source-like' based on the high or low density of physiological *traps* present in the organ, respectively, where *traps* refer to the physiological and anatomical components found in the microvasculature of the organs, e.g., vessel wall fenestrations, interendothelial gaps, or resident macrophages<sup>3-4</sup>. The classification of the organs was validated by the behavior obtained from the quantification of the SPECT/CT images. The sink-like organs, such as the liver and spleen, showed NP accumulation over time due to the activity of the traps causing NP retention in the extravascular space and thus loss of bioavailability. In contrast, in the source-like organs, such as the lungs, abdominal aorta, muscles, heart, and brain, the NP concentration declined with time showing an analogy to blood concen-



**Figure 1 | Integrated in vivo imaging and mathematical modeling. a) Regions of interest for investigation of MSN disposition kinetics. b) Schematic of organ classification in the context of whole-body disposition of MSNs. c) Representative SPECT/CT longitudinal images of an animal injected with 25 nm sized TMS-coated MSNs. d,e) One-compartment PK analysis of MSNs in the heart.**

tration kinetics, indicating that NPs in source-like organs traverse through the vasculature without getting trapped. The MSN concentration kinetics in various ROIs was modeled with the following double exponential function and its variants:

$C_i(t) = A \cdot (e^{-k_{out,i} \cdot t} - e^{-k_{in,i} \cdot t})$  (1) where  $C_i$  is the NP concentration in organ  $i$ ,  $A$  is the back extrapolated concentration of the decline phase at time  $t = 0$ , and  $k_{in,i}$  and  $k_{out,i}$  represent the uptake and elimination rate constant of NPs, respectively.

Further, to estimate pharmacokinetic parameters, a one compartment PK model was applied to the heart concentration kinetics data (surrogate for systemic blood kinetics) (Figure 1d,e). The fitted concentration-time curves demonstrate the effect of MSN size, surface chemistry, zeta potential, and route of administration on their systemic kinetics. For both routes of administration, the area under the curve of heart concentration-time curve showed a strong negative linear dependence on particle size, suggest-

ing that smaller size correlates with greater systemic bioavailability of MSNs. Furthermore, the trend in uptake rate constants suggested that the peritoneal cavity absorption of NPs following i.p. injection is independent of particle size, and the systemic bioavailability is primarily a function of the elimination rate parameter. The half-life ( $t_{1/2}$ ) results indicated that smaller size correlates with a longer  $t_{1/2}$ , and upon entering the blood stream, MSN kinetics is independent of the route of administration. This result emphasizes the in vivo stability of MSNs which is required for clinical translation. With respect to excretion, the TMS-coated MSNs of different sizes, regardless of the administration route, were excreted to comparable amounts. Finally, positively charged particles tended to be excreted out faster.

Through this study, we thus demonstrated the non-invasive imaging-based pharmacokinetic analysis of MSNs and established their SARs necessary for preclinical development and clinical translation.

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**Prashant Dogra**  
**Maria J. Pelaez**  
**Zihui Wang**  
**Vittorio Cristini**

Mathematics in Medicine Program,  
Houston Methodist Research Institute,  
Houston, TX 77030, USA

# The hunt for an alternative to century-old Type 1 diabetes treatment

Dr Elizabeth Robertson, Director of Research at Diabetes UK details the hunt for an alternative to century-old Type 1 diabetes treatment – and looks at how British diabetes research is demanding something better

Insulin has remained the only primary treatment for people with Type 1 diabetes since its discovery, nearly a century ago. The technology has changed and the insulin used is more effective, but the demands of insulin therapy on people with Type 1 are still too high.

Despite the significant improvements in healthcare for people with Type 1 diabetes, the majority continue to have blood glucose levels above the safe threshold. This means that they face an increased risk of complications, such as heart disease, sight loss and kidney damage. What's clear is that we need to find more effective ways to treat Type 1 diabetes.

As an alternative to replacing lost insulin, scientists are looking upstream for treatments that reach the underlying cause of Type 1 diabetes: an immune system attack against the pancreas. Could we protect the insulin-producing cells before they become damaged?

This is what new treatments – called immunotherapies – are designed to do and they are already licensed for other autoimmune conditions. Scientists hope that by, for example, retraining the immune system, the therapies could slow the progression of Type 1 diabetes, or even prevent it entirely.

Several immunotherapies have been shown to be safe and some – currently being tested in clinical trials for Type 1 diabetes – has promising evidence of their effectiveness in a laboratory environment. So why are there still no licensed immunotherapies for Type 1 diabetes? The answer is likely related to the complexity of the condition, the lack of investment in diabetes research and, critically, the limited time period in which trial participants can be recruited.

While global trials are underway to find therapies to prevent Type 1 diabetes, one UK initiative is attempting to speed up the development of immunotherapy for those living with Type 1 diabetes today.

## Changing the UK immunotherapy landscape

In 2015, Diabetes UK and JDRF established the Type 1 diabetes Immunotherapy Consortium. As a network of scientists and specialist labs working together, it aimed to enable immunotherapy research in the UK to thrive – and get the first immunotherapy for Type 1 diabetes licenced.

Over the last four years, the Consortium has set up trial sites across the UK. Each site has a specialist team to run immunotherapy trials and support recruitment, with a central team of expert scientists on hand to study and compare samples from different trials, to learn more about how the potential treatments work.

They have helped move the UK from a country struggling to deliver immunotherapy trials to one of the top recruiters in Europe. Now, the Consortium is ready to build capacity in order to meet the increasing recruitment needs for the trials in their pipeline.

That's why Diabetes UK and JDRF recently committed to co-funding the next phase of the Consortium, enabling the network to realise their ambitious plans. Professor Colin Dayan, the co-lead principal investigator of the Consortium, plans to: 1) Expand their network of research sites so that 50% of the UK population will live within 50 miles of a site, with the aim of recruiting 200 newly diagnosed children and 150 adults into trials each year; 2) Harmonise protocols across immunotherapy trials in order to reduce variation and facilitate the





*Dr Elizabeth Robertson*

Before the Immunotherapy Consortium, approximately 30 of every 3,000 eligible people diagnosed with Type 1 diabetes took part in a UK immunotherapy trial each year. To put this into perspective, one Phase I clinical trial testing the safety of a new treatment could require all 30. Licencing a new drug typically requires trials involving hundreds, if not thousands, of participants.

The Consortium hopes to further improve recruitment – they have already increased numbers fivefold since 2015 – but we are calling for greater awareness of immunotherapy trials amongst diabetes healthcare professionals. With such a tight recruitment window, we all need to take the time to ensure people newly diagnosed with Type 1 diabetes are aware of their options.

And for people diagnosed with Type 1 diabetes, taking part in an immunotherapy trial could be their best chance for a good start. Not only could they have access to potentially effective treatment, but they will also receive excellent clinical care and support at a crucial time in their diabetes journey.

Immunotherapies have the potential to revolutionise the way Type 1 diabetes is treated. If successful, they could lead to improved management and health outcomes in the near-term and hopefully to both preventative and curative measures in the long-term. But realising this potential requires research and healthcare communities to pull together – both in the UK and beyond. We believe that the scene is now set to transform the lives of people with and at risk of Type 1 diabetes. ■

pooling of data between different trials so that scientists can learn even more and finally; 3) Make each trial more efficient, so they can be conducted in half the time and with half the number of volunteers.

But the goal of licensed immunotherapy for Type 1 diabetes in the UK requires a concerted effort from across research and healthcare – and we need the help of healthcare professionals supporting people newly diagnosed with Type 1 diabetes.

### **Making the first 100 days count**

Immunotherapies for Type 1 diabetes are currently tested in people newly diagnosed – when they still have some working insulin-producing cells that haven't yet been destroyed by their immune system. This creates a challenging 100-day recruitment window after diagnosis, in which someone can take part in a trial. This tight recruitment window shrinks the pool of eligible participants and scientists believe this is holding back progress.

### **Dr Elizabeth Robertson Director of Research**

Diabetes UK

Tel: +44 (0)20 7424 1001

[www.diabetes.org.uk](http://www.diabetes.org.uk)

[www.twitter.com/erobertson02](https://www.twitter.com/erobertson02)

[www.twitter.com/DiabetesUK](https://www.twitter.com/DiabetesUK)

# Clinical Contract Research: Building the digital bridge between clinical research and clinical care

Prof Dr Freimut Schliess, Director, Science & Innovation at Profil GmbH, sheds light on how Clinical Contract Research Organisations are building the digital bridge connecting clinical research and clinical care, which includes discussion of a lack-of-data problem

**D**igitalisation is a mega-trend impacting almost all spheres of life and work. In the health-care sector, the sensor-based acquisition of health & behavioural data and the derivation of digital biomarkers as by pattern recognition and artificial intelligence (AI) tools is expected to revolutionise both clinical research and clinical care.

Health solutions driven by the exploitation of continuously captured person-generated health and behavioural data will improve the outcomes of both clinical research and clinical care. On the other hand, we see a lack-of-data problem, that is, limited availability and usability of person-generated real-world data.

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**“...the elements of the pay-for-performance culture widely established in clinical contract research could serve as a model for corresponding remuneration schemes in clinical care.”**

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In clinical drug development, the lack of real-world data accounts for a low predictive value of controlled clinical trials. This contributes to high attrition rates with a 50% failure of drug candidates even in phase III. What is even worse for patients and drug developers, more than 450 drugs were

required to be withdrawn from the markets between the 1950s and 2013. In clinical care a lack of realworld data usage contributes to the gap between the efficacy of investigational drugs and devices in well-controlled clinical trials and the effectiveness of marketed products in real-life.

## **Clinical contract research for cost-effectiveness in drug development & chronic care**

Clinical Contract Research Organisations (CROs) such as Profil have the capabilities to play a key role in improving cost-effectiveness in the healthcare sector. Based on Profil's experience with initiatives on the implementation of digital solutions in diabetes care like CLOSE<sup>1</sup>, iPDM-GO<sup>2</sup>, D4Kids<sup>3</sup> and AP@home<sup>4</sup>, we agree with drug developers and regulatory authorities in seeing a high need for integrating the acquisition of real-world data already in early phase clinical trials. Real-world data are accessible through the usage of medical-grade sensor systems which are fit-for-purpose and validated in the specific context-of-use. By measuring multiple parameters sensors should cover diverse domains of both drug safety and treatment-effect-modifiers. The early integration of real-world information will improve the quality of

the sponsor's decision-making on the (dis)continuation of clinical development programmes, thereby reducing failures in drug development with corresponding cost savings in the order of billions of euros.

Clinical CROs have the ambition of making a significant impact on the real-world effectiveness of treatments. One approach followed by Profil is to explore synergies from convergent trends in clinical research and clinical care by being part of innovation ecosystems provided by public-private partnerships such as EIT Health<sup>5</sup> and the Center of Competence for Innovative Diabetes Therapy.<sup>6</sup> Indeed, the diverse but complementary innovation initiatives curated by such partnerships integrate health industries, regional healthcare provision, data sciences and health economy, thereby create excellent ecosystems for jointly advancing the effectiveness of chronic disease management in a socially responsible manner.

## **CRO service enrichment brings the real world to clinical trials**

Taking the need for adding real-world experience to the well controlled trials clinical CROs are increasingly going to enrich their data management and statistic offers by creating a full



portfolio of real-world data acquisition and exploitation services. Service provision starts with a scientific, regulatory & legal consulting on real-world data acquisition and exploitation. It continues with a rational design of the real-world trial component, the corresponding enrichment of the data management and statistics plan, the selection and validation of appropriate sensor systems, the education of trial participants, and the operational implementation of real-world data acquisition including a remote monitoring of trial participants. Services culminate in the derivation and consolidated interpretation of digital biomarker signatures as documented in a real-world drug safety and efficiency dossier. In agreement with sponsors, well-reputed CROs can disseminate the real-world trial outcomes to the diverse stakeholder audiences including scientific and user communities and regulatory authorities.

It goes without saying that CROs like Profil have the capabilities to deliver services around real-world data in full compliance with the requirements imposed by law (e.g. the General Data Protection Regulation in Europe and the Health Insurance Portability and Accountability Act in the United States) and by regulatory authorities like FDA and EMA. This requires full

transparency in the documentation of source data and audit trails, quality assurance and data filtering. Pattern recognition tools or AI-based algorithms used for the derivation of digital biomarkers on real-world drug safety and effectiveness need to be transparently disclosed.

## The inspiration for clinical care from clinical contract research

Real-world clinical care can get inspiration from the collaboration with clinical CROs. The application of sensor-based technologies in the framework of professional clinical trial conduct may provide an ethical and operational blueprint for the exploitation of patient-generated data in clinical care. Clinical contract research has particularly high ethical standards when it comes to data management and statistical analysis, as well as data reporting and interpretation.

In order to inform the discussion with payers and medical associations, developers of real-world data acquisition and exploitation tools are well advised to initially go for the drug development market. Drug development could serve as a steppingstone to the much more complex outpatient and hospital care markets. Learning experiences and evidence for the

benefit of using digital biomarkers in clinical drug development will inform the discussions with medical associations, health technology assessment bodies and payers. By performing independent trials clinical CROs contribute to the social acceptance of digital health solutions for clinical care, sharpen their competitive edge and prove their eligibility for reimbursement.

Last but by no means least, the elements of the pay-for-performance culture widely established in clinical contract research could serve as a model for corresponding remuneration schemes in clinical care.

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**Prof Dr Freimut Schliess**  
**Director, Science & Innovation**  
 Profil GmbH  
 Tel: +49 2131 4018 225  
[Freimut.Schliess@profil.com](mailto:Freimut.Schliess@profil.com)  
[www.profil.com](http://www.profil.com)



# Medication management in diabetes

PillTime Ltd highlights the importance of medication management for diabetes as it remains a significant burden on the NHS

As we look to the future of the NHS, diabetes remains a significant burden. Estimates show that as many as five million people in the UK will have diabetes by 2025.<sup>1</sup> By any standards, this is a huge diabetic population.

Every year, the NHS spends at least £10 billion on treating diabetes. That's an unfathomable £1 million every hour.<sup>2</sup> The financial implication of diabetes to the NHS is great. Yet, it's not the cost of treating the illness itself that is so encumbering. The complications that arise from poorly-managed diabetes are vast and costly. A 2012 report from the London School of Economics sheds light on the issue. It estimates that diabetes complications cost around three to four times more than the cost of prescribing diabetes medication.<sup>3</sup>

Diabetes complications include blindness, amputation, heart disease and stroke. These outcomes can be devastating to sufferers and family members. They also place undue pressure on the NHS.

## **The bitter pill to swallow? These dangerous and expensive complications are, most often, entirely preventable**

People with diabetes can control their condition by taking good care of themselves. This includes eating a healthy diet, being active and taking the correct medication. These are all ways to maintain safe and stable

blood sugar levels. This, in turn, reduces the risk of extensive health issues. Diabetic people can live long and healthy lives with the illness.

In spite of this, medication adherence amongst Type 2 diabetics (T2D), in particular, is low. More than 500 people with diabetes die prematurely every week. On average, one in six hospital beds is occupied by someone with diabetes.<sup>2</sup>

## **Why is medication management so poor and how can we improve it?**

People with diabetes often have several medications to manage their symptoms, as well as their blood sugar. Plus, T2D often arises from a poor lifestyle and obesity. Because of this, people with T2D may likely be managing other associated health issues. Common troubles include high cholesterol, high blood pressure and issues around mental health. This can add an extra layer of daily medication on top of an already hefty diabetes treatment plan.

When taking an array of different prescription drugs, it's easy to get things wrong. People often miss doses or take the wrong thing altogether. Organising many medications can be confusing and time-consuming. As an experienced pharmacist, I've known many patients who struggle to manage their doses. I've even seen medication wrapped in stray bits of

tin foil, unlabelled, used as a dose solution. Dose-sorting needs to be rigorous and thoroughly checked. Patients are not always able to do this for themselves.

## **Medication non-adherence: The risks**

For decades, healthcare professionals have been aware of these issues. Poor medication adherence isn't exclusive to people with diabetes. In fact, more than 50% of people take their medication incorrectly. This figure increases with age and the number of items a person takes.<sup>4</sup> If people don't take their medication as instructed by their doctor, they do not get the full benefit of it. They may also be putting their health at risk.

Poor medication management can have severe consequences. These include withdrawal symptoms, poor condition control and hefty NHS costs. Wasted medication alone costs the NHS over £300 million every year.<sup>5</sup> That's before the cost of hospital and GP resources needed to treat people who are suffering as the result of poor medication management. The NHS can't sustain these avoidable burdens. As we take on the NHS's Long-Term Plan, it's imperative that we tackle adherence in a holistic way.

## **The limitations of compliance aids for diabetes medication**

Traditional compliance aids, such as dosette boxes, are used to help tackle



to problem. However, these aids can often present further challenges. Medication is personal; everyone's needs, lifestyles and struggles are different. Dosette boxes don't account for this and may result in people incorrectly amending their doses to fit into rigid dosing times. Plus, not everyone wants to lug their whole week's worth of medication around. It's inconvenient to crack open a medication tray at a business meeting, a coffee date or the gym. This can deter people from taking their dose when they need it.

## **PillTime has revolutionised medication management**

Now there's a free solution that revolutionises medication management, once and for all. We created PillTime digital NHS pharmacy in 2016. Ever since, we have been helping thousands of people manage their prescription. We dispense everything needed for one dose into a clearly-labelled, easy open pouch. The whole prescription is organised onto a reel of pouches, in the order they need to be taken. So, patients simply tear off their required pouch, and the rest

stays organised in their PillTime box. We use robotic technology and image recognition to sort and check the pouches as part of a rigorous checking process.

## **How does PillTime help improve diabetes medication management?**

It removes the hassle and confusion. We organise everything for our patients. So, there's no need to worry about sorting doses and working out the best time to take it. We take personal needs into account and clearly label each dose with a person's name, their time of dose and a full description of the contents. This way, it's plain to see what's required and when. In addition, medication management is no longer restrictive. Our pouches can be taken on the go, so there's no compromise between lifestyle and health.

PillTime's personalised solution is ideal for people with diabetes. As well as the pouches, we deliver all prescription items in one free delivery. A PillTime delivery contains all non-tablet medication, such as injections and testing

strips. By making prescriptions hassle-free, convenient and personalised, we remove everyday obstacles that arise for people taking several medications. Our pouches fit seamlessly into people's routines. When medication simply becomes part of someone's day, they are more likely to take it properly. This in turn, aids condition management and reduces the need to seek medical help.

PillTime makes managing multiple medications simple. To find out more about our free service, or to enquire about working with us to help improve adherence and reduce NHS costs, visit our website, at [www.pilltime.co.uk](http://www.pilltime.co.uk).

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**Hannah Matthews**  
**Marketing Executive**  
 PillTime Ltd.  
[HCP@pilltime.co.uk](mailto:HCP@pilltime.co.uk)  
[pilltime.co.uk](http://pilltime.co.uk)  
[www.twitter.com/pilltimeuk](https://twitter.com/pilltimeuk)



# Diet and Type 2 diabetes: Why a person should never be judged on what they eat

The iDEAL group shares their thoughts on diet and Type 2 diabetes and explain why a person should never be judged on what they eat

Dealing with judgemental comments on diet and lifestyle are, for many people with weight management issues, an all too normal part of life. Obesity stigma is everywhere; research suggests 18.7% of obese people in one Western European country experience “weight bias”, rising to as many 38% of severely obese people.

For some of those who also live with Type 2 diabetes, such scrutiny of everyday choices can be still more intense, with family members, healthcare professionals or complete strangers casting aspersions on what they might happen to be eating and how it impacts on their condition. The increasing prevalence of words and phrases implying blame on an individual for what they eat – “guilt-free”, “guilty pleasure” – do little to mitigate the problem.

The UK’s Language Matters group (2018), made up of experts in diabetes care and patient advocates, have done sterling work in raising awareness of why a whole range of oft-used words and phrases in the context of diabetes (“non-compliant”, “burdened”, “uncontrolled”) can inadvertently imply blame on the part of the individual. The Language Matters position statement (2018) supports healthcare professionals to consider and develop the language used in consultations and interactions with people with diabetes to be supportive and empathetic.

The problem of bias, though, runs deeper than in our choice of language. Sometimes, our attitude to Type 2 diabetes and lifestyle, in general, does not reflect the complex and varied challenges that can prevent somebody with Type 2 diabetes – or indeed, anybody else –



from eating certain kinds of foods. There can be all kinds of reasons a person isn't eating healthily; societal, economic, cultural and other factors can all play a role, an issue compounded when a person is balancing a number of competing agendas in their lifestyles (Franklin et al, 2018).

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**“With such widespread health inequalities in the UK, many people with Type 2 diabetes may well be more concerned about keeping a roof over their head than they are about managing their condition. It’s very complex – we all have a choice every day in what we put into our mouths, and some of us are very lucky to have the privilege of being able to buy certain foods in certain places. But not everyone is able to do that, and there’s a lot of judgement in that.”**

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One of the most common factors preventing a person with Type 2 diabetes from eating healthily is the cost of doing so; according to one study, a “healthy” diet now costs on average three times as much as an “unhealthy” diet and that gap is widening. With around 8.4 million people in the UK living in food insecurity, one of the highest levels in Europe, increasing spending on food by a multiple of three may not be entirely feasible. Such inequalities in the UK are becoming increasingly stark, with disproportionately high levels of Type 2 diabetes diagnoses in areas with the biggest socio-economic challenges (Qi et al, 2019).

In these areas, research shows, you’ll find five times as many food outlets that can be defined as “unhealthy” and you’re also more likely to live within 500 metres of one of them. In some, such as Blackburn with Darwen, up to 38% of all food retail outlets are fast-food takeaways.

“This is bigger than we are,” says iDEAL panel member and dietitian specialising in diabetes Anita Beckwith. “With such widespread health inequalities in the UK, many people with Type 2 diabetes may well be more concerned about keeping a roof over their head than they are about managing their condition.

“It’s very complex – we all have a choice every day in what we put into our mouths, and some of us are very lucky to have the privilege of being able to buy certain foods in certain places. But not everyone is able to do that, and there’s a lot of judgement about it.”

Dietitians can be transformative in Type 2 diabetes care pathways; in consultations they make recommendations on how a person can fit healthier meals into their own unique, individual circumstances, increasing the likelihood of success.

Taking economic and other individual factors into account is crucial; a person needs to be able to sustain a diet in order to reap from it any substantive health benefits. It’s, therefore, important to make dietary recommendations on a case by case basis, rather than issuing blanket advice that won’t be applicable for many people – especially those who are facing health inequalities or are from different ethnic backgrounds (Goff, 2019).

“Talking to someone about how they’re eating can be quite challenging as a dietitian because people automatically think we’re the food police,” Anita says. “They think it will be very much about calories and good and bad foods. Their attitudes towards food will be influenced by their upbringing, where they are in their life at the moment, and what their societal norms are. So offering guidance on diet can be a very interwoven discussion – we have to break it down into what it is achievable and recognising what they’re able to do.”

Anita’s approach can be highly beneficial in supporting a person with Type 2 diabetes effectively; the way to facilitate positive change is not through reprimanding, judgement or dictation, but through person-centred guidance that gives people the ability to make a lifestyle change that’s right for them. The bottom line is this: people with Type 2 diabetes have the right to live their lives without the fear of being judged for what they eat. We must remember that. ■

The iDEAL Group is supported by an unrestricted educational grant from Ascensia Diabetes Care.

iDEAL Group  
 idealdiabetes@createhealth.io  
<http://idealdiabetes.com>  
[www.twitter.com/idealdiabetes](http://www.twitter.com/idealdiabetes)

# From diabetes prevention 1.0 to Prevention 3.0

Digitally enabled pathway personalisation is leveraging actionable data insights and dynamic intelligence to drive better outcomes as part of the Prevention 3.0 agenda

**W**hen it comes to the case for diabetes prevention, we know that the rising global prevalence of Type 2 diabetes has placed acute strain on healthcare budgets, attracting the attention of US and UK policymakers.

The US National Diabetes Prevention Program established credible evidence linking lifestyle change with reducing risk of Type 2 diabetes onset, leading policymakers in the UK to establish the NHS England Healthier You Diabetes Prevention Programme.

Early provision, or prevention 1.0, was geared to helping those identified with elevated blood sugar levels to create a lifestyle change plan in face-to-face settings.

Prevention 2.0 built on this by leveraging telehealth and nascent digital-enablement to reinforce face-to-face provision with remote support.

## Pushing the boundaries of the possible

Hitachi's diabetes prevention journey started in 2010, when the company developed its first digitally-enabled service to support its employees in meeting their wellness goals. Hitachi's programme attempted to move provision towards telehealth and digital-enablement, or prevention 2.0.

By bringing together a blend of

telehealth coaching and digital tools, Hitachi was able to personalise the provision of care, while giving its employees the means to effectively self-manage their lifestyle changes.

Since 2010, the solution has been rolled out to other Japanese corporates and used as a foundation for Hitachi's collaborations with the NHS in England, aimed at leveraging clinical expertise, remote telehealth and digital solutions to create a new model of provision, or Prevention 3.0.

## Actionable data insights and dynamic intelligence

Hitachi's Smart Digital Diabetes Prevention solution, underpinned by its Prevention 3.0 vision, firmly establishes data as a critical enabler for improving service performance and patient outcomes. Developing an appropriate data lake consisting of cohort, progress and engagement data (to be described in the forthcoming OAG e-book due to be published in October 2018) is the first step towards delivering dynamic intelligence.

The next step is to surface data insights through advanced analytics and combine these with qualitative analysis, using user-centric design methods and a co-creation approach with commissioners, digital teams and frontline NHS health advisers to identify opportunities and strategies for service improvement.

## Service personalisation

Actionable data insights and dynamic intelligence allow Hitachi and its clinical partners to help support personalised service provision, so that appropriate support is provided to patients at the right time. This helps to ensure that patients' needs and preferences drive health adviser engagement and coaching, providing patients with the best opportunity to achieve positive outcomes (reduction in risk of Type 2 diabetes onset), while furnishing the service with the intelligence needed to ensure constrained resources are targeted to those with the greatest need.

Examples of how Hitachi's Smart Digital Diabetes Prevention solution has leveraged actionable data insights and dynamic intelligence to support service personalisation include:

- Personalisation of patients' lifestyle change goals based on cohort and presenting needs data captured through an online self-assessment and processed with algorithms.
- Personalisation of the health adviser dialogue with their patients based on cohort and progress data, such that it focuses in on the greatest areas of need.
- Personalisation of the pathway based on population-level cohort insights, such that patients who require more intensive health adviser

support receive it at the right time, while allowing those who can self-manage do so.

**Hitachi's Smart Digital Diabetes Prevention solution leverages actionable data insights and dynamic intelligence to help support personalised service provision at patient and population level to improve health outcomes and optimise allocation of resources to support defined areas of need.**

## Service improvement

Actionable data insights and dynamic intelligence allow Hitachi to better understand how patients engage with digital tools, allowing an agile continuous service improvement agenda to be implemented. The latter includes enhancement to both the digital tools and the coaching and education delivered by health advisers, to respond quickly to needs identified at population, cohort and patient levels. Examples of how Hitachi has leveraged actionable data insights and dynamic intelligence to support service improvement include:

- Evolving health adviser and patient dialogue from a transactional to transformation dialogue, whereby the dialogue is focused on addressing the individual lifestyle needs rather than a mere description of lifestyle habits, thus ensuring patient support is as personalised as possible.
- Ensuring that minority cohorts (such as those with limited access to digital tools and limited IT literacy) can engage with the pathway and receive additional support where appropriate.

- Evolving the digital tools to promote active patient engagement while in service. This includes the design of new features, auto-generated behavioural prompts and signposting to appropriate and tailored structured lifestyle information.

**Hitachi's Smart Digital Diabetes Prevention solution leverages actionable data insights and dynamic intelligence to enhance the scope and impact of continuous service improvement activity to help ensure that support offered to patients continues to evolve in line with best practice and patients' engagement with the digital service.**

## Commissioning of services at population level

Commissioners at national, regional and local levels are eager to ensure the services they procure address population needs, while remaining flexible to meet needs at more discrete levels. While 'hard' clinical data offered by service trials and clinical studies continues to be the gold-standard for decision-making:

- Commissioning organisations are finding it increasingly difficult to commit both the funding and resources required to deliver them.
- The timescales prohibit rapid delivery of data insights in what is a very fast-moving digital healthcare economy.

This means that commissioners are turning to both qualitative and quantitative data-points established through patients' engagement with digital tools, thereby allowing them to access dynamic intelligence at lower

cost. Hitachi's Smart Digital Diabetes Prevention solution provides data insights that can help commissioners realise these objectives:

- Providing access to dynamic intelligence that identifies opportunities for developing new and integrated services and/or transforming existing service offerings to ensure maximum reach and outcomes for patients.
- Allowing dynamic intelligence to be accessed throughout the service management lifecycle, allowing commissioners to ensure that services evolve with the regional and/or local healthcare economies.
- Informing both the 'hard' and 'soft' metrics commissioners build into future service contracts to ensure they are meeting the needs of their populations at optimal cost.



Hitachi Consulting  
Tel: +44 (0)20 7842 7800  
healthcare@hitachiconsulting.com  
<http://bit.ly/HSDDP>  
[www.twitter.com/HIT\\_Consulting](http://www.twitter.com/HIT_Consulting)





# Diabetes focus: The role of nutraceuticals in preventing illness

Pete Tate, CEO and Founder of MedTate, explains the role of nutraceuticals in preventing illness when it comes to diabetes in the UK

**D**iabetes has reached such a high in the UK that all of the people diagnosed with the disease would be enough to fill Wembley Stadium more than 52 times over, that's according to recent statistics from the charity Diabetes UK. The number of people diagnosed with diabetes in the UK more than doubled between 1998 and 2018, with the figure standing at 4.7 million in the latter year. With an already huge jump in the number of people diagnosed, it is arguably unlikely that fewer people will be diagnosed this year. While diabetes medication is on hand for all these individuals who become diagnosed, it's time to take more of a preventative stance on the disease.

As a nutraceutical company, we believe that it is the responsibility of the government and nutraceutical industry to educate the public about health and wellness. It is ingrained into my ethos to help maintain wellness and help individuals prevent illnesses and I do what I do today after gleaning the inspiration from my grandfather, L K Tate, who experimented in Ayurvedic medicine with the ambition to cure himself of diabetes. My grandfather lived to 100-years-old and he believed that it was the power of natural herbs that helped him live a long life. His attitude inspired me to think about how natural supplements can be used to maintain healthy lives.

Our ethos is essentially that prevention is better than cure, as most prescription medicines do not cure, they just treat and maintain. As is the case with many organisations today, we are determined to change attitudes and encourage everyone to do more to prevent illness and to take an active role in establishing a healthy society.

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**“The number of people diagnosed with diabetes in the UK more than doubled between 1998 and 2018, with the figure standing at 4.7 million in the latter year. With an already huge jump in the number of people diagnosed, it is arguably unlikely that fewer people will be diagnosed this year. While diabetes medication is on hand for all these individuals who become diagnosed, it’s time to take more of a preventative stance on the disease.”**

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Individuals looking to ensure that their health is in good condition so that they can live long, healthy lives can do their own bit to prevent illness in the future. We work closely with pharmacists and know that they have seen a rise in the number of people coming into their stores to ask for wellness supplements. The conversation on wellness is growing to such an extent and people are actively seeking not just supplements but also advice from their pharmacists on how to cultivate their own wellness routine. For example, rather than going to their doctor if they feel frequently tired or feel a cold coming on, pharmacists have said people are seeking supplements rather than medicine.

This increased public awareness is leading to a booming nutraceutical market which is host to a series of industry players with the mission of helping prevent illness. The global nutraceutical market was valued at around \$383.06 billion in 2017 and is expected to reach approximately \$561.38 billion by 2023. This is indicative of the role that nutraceutical companies, like MedTate, are playing in helping drive health and wellness in the public. This increased drive for awareness of supplements that can be taken to support health will only lead to a healthier society. While nutraceuticals do not have the capacity to cure illnesses like diabetes, they do have a crucial part to play in helping prevent them.

Type 2 Diabetes is largely preventable as are other life-changing illnesses and there is room for nutraceutical companies to drive prevention. There is currently a strain being placed on the NHS in providing prescribed medication to the public, worryingly this comes amid an epidemic which is seeing individuals become reliant on medication. With this increased pressure being placed on the NHS, our goal is to help prevent illness so that this strain is alleviated and the number of people living with illness declines.

We have already seen concerning reports regarding antibiotics and the dangers of them becoming ineffective due to heavy public consumption. It is clear that prescribed medication should be reserved to a last resort and that the onus is on individuals and medical professionals to ensure enough is done to avoid having to rely on prescription drugs.

We are putting together a range of educational resources with the aim of educating individuals and pharmacists about the ways in which they can safeguard themselves against becoming ill. Nutraceuticals are not offering a cure but instead presenting an opportunity to drastically reduce public risk of life-threatening illnesses. ■

**Pete Tate**  
**CEO and Founder**

MedTate

Tel: +44 (0)207 112 5138

[info@medtate.co.uk](mailto:info@medtate.co.uk)

[www.medtate.co.uk](http://www.medtate.co.uk)

[www.twitter.com/medtateuk](https://www.twitter.com/medtateuk)

# Diabetes and rationing in the UK

Jenny Hirst MBE, Co-Chair, highlights the charitable work involved at InDependent Diabetes Trust to support people living with diabetes in the UK

I am Co-chair of the InDependent Diabetes Trust which is a patient-based registered charity entirely funded by voluntary donations aiming to provide information and support to people living with diabetes and to listen to and represent their needs.

My involvement with diabetes started in 1975 when my daughter was diagnosed with Type 1 diabetes (T1D) at the age of five years. It was a time of long needles, glass syringes and urine testing.

**“On March 7th 2019, NHS England published the criteria for people with T1D to obtain the FreeStyle Libre free on the NHS but it is difficult to understand the logic or the fairness of these criteria.”**

This was a generation who had to fight for everything, we battled to obtain disposable syringes free on an NHS prescription. When blood glucose reagent strips came in for home blood glucose monitoring, we battled to obtain them free on the NHS but in the meantime, we cut the strips in half so that we got twice as many tests from one pot of strips!

For people living with diabetes, home blood glucose monitoring was the major change in managing blood glucose levels because for the first time, they knew what was happening to their glycaemic control. It also changed the lives of parents and partners,



because they could carry out tests when their family member was hypo- or hyperglycaemic and deal with those situations much better. So, the quality of life improved for everyone.

## The battles are still going on...FreeStyle Libre

The FreeStyle Libre flash glucose monitoring system is the latest innovation. This device means that finger-prick blood glucose tests people carry out four to 15 times a day can be replaced with a sensor on the arm which is scanned as often as required. This method is less intrusive, less disruptive and without pain!

On March 7th 2019, NHS England published the criteria for people with T1D to obtain the FreeStyle Libre free on the NHS but it is difficult to understand the logic or the fairness of these criteria.

For instance, children and adolescents with T1D are not included, yet this is a group who really need this device both for comfort and to encourage them to test more frequently.

Equally, there is no mention of other co-morbidities which make glycaemic control more difficult and nor does it mention people with Type 2 diabetes (T2D) who are treated with insulin and therefore need to self-monitor.

In 2019/20, the maximum amounts that Clinical Commissioning Groups (CCGs) will be reimbursed for the ongoing costs of the Libre sensors will be up to 20% of their T1D population. While there will no longer be a postcode lottery of availability as promised, availability is being rationed to 20% of people with T1D in each CCG. For instance, in Darlington



CCG the 20% figure is 112 patients with T1D, so what happens if you are patient number 113 but still fit into the criteria for the Libre on the NHS?

## Type 2 diabetes and monitoring

The vast majority of people with T2D who are not taking insulin are not allowed blood glucose test strips on the NHS because research suggests that testing does not improve overall blood glucose levels. This decision fails to recognise that some people feel safer knowing what their glucose levels are, especially if they live alone.

Recently people in this group who have been using test strips for many years are being informed that they can no longer have them.

Understandably, they no longer know how they are now supposed to control their diabetes. Recommendations are that average blood glucose levels are measured by HbA1c tests carried out every three to six months. This may be satisfactory if people actually have their HbA1c tested every three to six months, but this does not always happen so people can go months not knowing what their level of control is!

## Cataract surgery restricted

People across England are being denied vital cataract surgery by their local CCGs. Research by the Medical Technology Group (MTG) in March 2019 has shown that 104 of the 195 CCGs in England restrict access to cataract surgery by including this on their lists of 'Procedures of Limited Clinical Value'.

These lists are normally reserved for complementary therapies or cosmetic procedures where there is little evidence to prove their cost effectiveness or clinical benefit. Yet in the national clinical guidelines published by the National Institute for Health and Care Excellence (NICE) in 2017, the cost effectiveness of cataract surgery, is stated as having 'a high success rate in improving visual function, with low morbidity and mortality'.

**"The vast majority of people with T2D who are not taking insulin are not allowed blood glucose test strips on the NHS because research suggests that testing does not improve overall blood glucose levels."**

Cataracts are part of the natural ageing process that applies to everyone, the only thing that varies is the age of onset. Cataract surgery is a simple operation with low risk but without it, people have visual impairment and blindness. With surgery, people can maintain their vision, their independence, their employment, a reduction in the risk of falls and do not have to claim benefits. Restriction of cataract surgery is rationing, short-termism and does not consider quality of life.

## Footcare for people with diabetes

The number of amputations among people with diabetes is continuing to increase and while there are changes for emergency care of feet in hospital when a crisis happens, there is a lack of NHS podiatrists in the community to help to prevent the damage occurring in the first place. Once again, this

appears to be a cost-cutting exercise that in the long-term does not save money and certainly is detrimental to the quality of life of the affected people with diabetes.

In making such decisions, there are common factors that CCGs do not appear to be considering, the quality of life of people with diabetes treated with insulin. The term 'quality of life' should not be taken lightly. Let us just look at what living with this condition means for children and adults: at least four injections a day, four to 15 finger-prick blood tests a day, living with the daily fear of hypoglycaemia, the risks of diabetic ketoacidosis and the fear of, and sometimes the reality, of long-term complications and higher than average rates of depression. Add to this that there are options to make this life easier and improve the quality of life, but CCGs and NHS England are rationing these options. They should think again.



**Jenny Hirst MBE**

**Co-Chair**

Independent Diabetes Trust

Tel +44 160 462 2837

[jenny@iddtinternational.org](mailto:jenny@iddtinternational.org)

[www.iddtinternational.org](http://www.iddtinternational.org)

# How diabetes can affect the eyes

With diabetes on the increase in the UK, Dr Louise Gow, Specialist Lead for Eye Health at The Royal National Institute of Blind People (RNIB) explains more about the condition and how it can affect the eyes

Sight loss is one of the many complications of uncontrolled diabetes. People with diabetes are known to be more at risk of developing eye conditions, such as cataracts, glaucoma, or retinal vessel occlusion. However, the most significant risk to vision in people with diabetes is diabetic retinopathy. This is when the blood vessels on the retina, at the back of the eye, can become blocked or leaky.

The highest risk factors for developing diabetic retinopathy are the length of time with the disease and poor control of the condition or blood pressure. Other risk factors are pregnant women with Type 1 diabetes and those with associated kidney disease, nephropathy.

The stages of diabetic retinopathy are background, pre-proliferative and proliferative retinopathy. Background changes do not usually affect sight but need to be monitored carefully to make sure the changes do not get worse. This stage is a weakening of retinal capillaries leading to the development of small areas of swellings in their walls, known as microaneurysms. A microaneurysm may leak blood (haemorrhage), as well as fluid (exudate). Pre-proliferative change is a progression of this where widespread changes are developing.

Proliferative diabetic retinopathy is diagnosed when these changes affect a large area of the retina and the blood supply to it is reduced. This is called ischaemia. The body tries to fix this by growing new retinal blood vessels. Unfortunately, these new vessels are weak and they haemorrhage very easily over the surface of the retina (damaging the retina) or into the vitreous gel obscuring the vision. If this progresses fibrous bands form in the vitreous that can pull on the retina causing the retina to detach resulting in severe sight loss. In addition,

new blood vessels can also grow at the iris, which can cause eye pressure to rise and lead to glaucoma.

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**“The UK is one of few countries to offer routine eye screening for diabetic eye disease free of charge. All diabetics over the age of 12 are offered this service if they are not under the care of a hospital eye clinic. The screening ensures patients are informed of the early signs meaning they can make necessary changes to how they control their diabetes.”**

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Diabetic maculopathy occurs when the macula (central part of the retina) is affected by retinopathy. This means that central vision, which is required for seeing fine detail and colour, will be blurred. Fluid can build up at the macula called macular oedema. This causes vision to be blurred and distorted, as well as making colours appear washed out. The area can become ischaemic and the central vision lost.

Diabetic retinopathy may be treated with a focal laser for localised changes. This treats only small areas of the retina. When the disease is more advanced pan laser photocoagulation is used and treats a large area of the retina. Pan-retinal laser treatment itself can cause loss of peripheral vision but without treatment, the retinopathy will progress to cause a more serious loss of vision.

In advanced retinopathy surgery called vitrectomy where the vitreous gel from the eye is removed, may be required. This removes the fibrous bands to reduce the risk of detachment. Diabetic macular oedema can be treated with anti-VEGF injections.

It is thought that one in five people with severe sight loss will experience a condition called Charles Bonnet

Syndrome (CBS). These are visual hallucinations, with no other sensory element. They take the form of simple patterns or lights but can also be detailed or elaborate images and can occur on a frequent or intermittent basis.

Often people who develop CBS think they are developing a mental health condition or dementia and are reluctant to seek help. This is further impacted by a lack of awareness of the condition by medical, allied and eye health professionals. This results in unnecessary distress for the patients. Raising awareness in these professions would result in better patient care.

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**“With rising levels of diabetes, how the NHS manages capacity to ensure people can access eye screening and treatment when they need it is under increasing scrutiny. People with diabetes are currently called to have an eye examination every 12 months, but this is likely to be widened to two years in patients who have no sign of retinopathy or are at low risk.”**

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There is no medical cure for CBS but knowing CBS usually improves with time and having information on it, as well as sharing experiences with friends or family can also help. There are some management techniques that can be helpful, such as changing the light, reaching out to touch the image or staring straight at it to make the hallucination disappear.

Although it was once the leading cause of sight loss in the working age population, incidents of diabetic retinopathy are now declining due to earlier intervention, diabetic retinal screening and new treatment options.

Sight loss from diabetic retinopathy can be significantly reduced if identified and treated early. As symptoms are not present in the early stages it is very important that anyone with diabetes has regular eye examinations and attends their retinal screening appointments. The UK is one of few countries to offer routine eye screening for diabetic eye disease free of charge. All diabetics over the age of 12 are offered this service if they are not under the care of a hospital eye clinic. The screening ensures patients are informed of the early

signs meaning they can make necessary changes to how they control their diabetes.

However, as people can choose to opt out of the screening process the challenge is to try to educate those who are high risk or encourage those who are in hard to reach groups to attend their appointments. It is critical that people with diabetes are supported to manage their eye health, as well as controlling their diabetes.

It is hoped that new technologies, such as Optical Coherence Tomographers (OCT) will soon be introduced for eye screening programmes. These machines enable a non-invasive high-resolution view of the layers of the posterior pole of the eye and optic nerve head. They can potentially allow even earlier detection of retinal and macular changes.

With rising levels of diabetes, how the NHS manages capacity to ensure people can access eye screening and treatment when they need it is under increasing scrutiny. People with diabetes are currently called to have an eye examination every 12 months, but this is likely to be widened to two years in patients who have no sign of retinopathy or are at low risk. ■

*For more information on eye health visit [www.rnib.org.uk](http://www.rnib.org.uk)*

**Dr Louise Gow**  
**Specialist Lead for Eye Health**

The Royal National Institute of Blind People (RNIB)  
[www.rnib.org.uk](http://www.rnib.org.uk)  
[www.twitter.com/rnib](https://twitter.com/rnib)



# The role of TXNIP in mitochondrial-lysosomal axis dysregulation in diabetic retinopathy

Lalit P. Singh, Associate Professor (Department of Ophthalmology, Visual and Anatomical Sciences (OVAS) at Wayne State University School of Medicine, explains the role of TXNIP in mitochondrial-lysosomal axis dysregulation in diabetic retinopathy

**D**iabetic retinopathy (DR) is a devastating disease affecting millions of people around the world, leading to blindness. Yet, there is no known cure till today. Diabetes is mainly of two types – Type 1 diabetes (insulin deficiency due to pancreatic beta cell death, an autoimmune disease, T1D) and Type 2 diabetes (insulin resistance, T2D) often associated with obesity. Whether it is T1D or T2D, sustained hyperglycaemia prevails in the blood and causes tissue injury.

Currently, the mechanism(s) for the initiation and progression of DR is not fully understood. One gene that is strongly induced by diabetes and high glucose in tissues, including pancreatic beta, renal and retinal cells, is the thioredoxin interacting protein (TXNIP). TXNIP causes cellular oxidative stress, low-grade inflammation, cell death in DR.

TXNIP binds to thioredoxin (Trx), inhibiting its anti-oxidant and thiol-reducing capacity. Trx1 is present in the cytosol/nucleus while Trx2 is in mitochondria (Fig. 1-I). Another cellular anti-oxidant system is the glutathione/glutathione peroxidase (GSH/GPX). However, under chronic hyperglycaemia, TXNIP continues to inhibit Trx1 and Trx2 causing cytosolic and MT reactive oxygen species (ROS) generation. Stressed mitochondria are inefficient in ATP synthesis while generating ROS. Therefore, removal of

the damaged mitochondria is critical for cellular and MT health. For this, the damaged part of the mitochondrion is first separated by fission involving dynamin-related protein, DRP1 and fission protein, Fis1. Then, isolated mitochondria are removed by mitophagy (a specific process of autophagy) via lysosomal degradation.

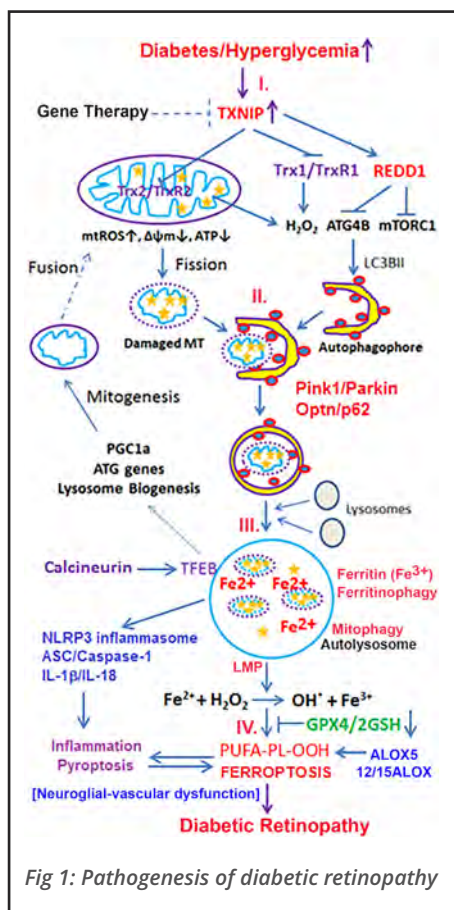
The retina being a part of the central nervous system consumes large amounts of glucose and oxygen for its bioenergetics and visual function via the MT inner membrane electron transport chain (ETC). During ATP production, electrons leak, which are captured by O<sub>2</sub>-generating ROS. Although there are anti-oxidants in both the cytosol and the mitochondrion, they are overwhelmed by sustained blockade of the Trx-TrxR system by TXNIP. This leads to overutilisation of GSH.

Ultimately, MT damage occurs, which needs to be cleared by mitophagy, a complex process yet to be fully understood. Briefly, upon MT damage, PTEN-induced kinase 1 (Pink1) accumulates on the outer membrane and phosphorylates membrane proteins, which attract Parkin (an E3 ubiquitin ligase) marking for degradation (Fig. 1-II). TXNIP also interacts with REDD1 (regulated in development and DNA damage 1) and inhibits mTORC1 (mechanistic target of rapamycin complex 1), which phosphorylates ATG1 (ULK1) and ATG13 to block autophagy/mitophagy.

Furthermore, TXNIP/REDD1 inhibit ATG4B, which delipidates LC3B-II in autophagophore; thereby increasing double membrane autophagophore formation. Then, mitophagy receptors, optineurin and p62/sequestosome 1, are phosphorylated by TANK-binding kinase 1 (TBK1) enhancing their interaction with MT cargo and LC3B-II and mitophagophore formation.

The mitophagophore then fuses with lysosomes to form the autolysosome, which degrades the MT cargo. Disturbance of the lysosomal membrane by autophagy/mitophagy causes translocation of transcription factor EB (TFEB) to the nucleus and enhanced transcription of lysosomal and ATG genes and PGC1 $\alpha$ , an MT biogenesis factor (Fig. 1-III). Although new mitochondria are generated, fusion with existing mitochondria to form functional MT network may be blunted due to MT stress.

Accumulation of fragmented mitochondria leads to bioenergetics deficiency. One aspect of TFEB regulation under mitophagy is that TFEB is phosphorylated by mTORC1 including at Serine 211 and sequesters in the cytosol via interaction with 14-3-3 scaffold protein while calcineurin-mediated dephosphorylation of TFEB leads to nuclear translocation and expression of CLEAR (Coordinated Lysosomal Expression and Regulation) genes. Which of the two proteins – mTOR or



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calcineurin – dominates the TFEB regulation in DR is yet to be defined?

Another consequence of sustained oxidative stress and mitophagic flux in cells is the accumulation of damaged mitochondria, membrane lipids, oxidised proteins, free iron and  $H_2O_2$  causing lysosomal enlargement, destabilisation and membrane permeabilisation (LMP) (Fig. 1-IV).

Mitochondria are major sites of iron metabolism including iron-sulphur cluster/complex biosynthesis, heme synthesis and storage in MT ferritin. MT TCA cycle enzyme (m-aconitase/ ACO2), Complexes I and III all contain 4Fe-4S clusters. In the cytosol, c-aconitase (ACO1) also contain 4Fe-4S cluster and serves as a dual function protein – (i) conversion of citrate to isocitrate and (ii) as an iron regulatory protein 1 (IRP1)

in the absence of iron-sulphur. Under oxidative stress or hypoxia, 4Fe-4S complex in ACO1 is degraded and IRP1 binds to iron regulatory elements (IRE) in the 3'-UTR of transferrin receptor 1 (TfR1) mRNA and stabilises to increase TfR1 translation and iron uptake. Cytosolic iron is stored in ferritin (ferric iron,  $Fe^{3+}$ ) and iron utilisation requires autophagy of ferritin (ferritinophagy) to generate free/labile ferrous  $Fe^{2+}$ , which is highly reactive with  $H_2O_2$  (Fenton reaction) to generate reactive hydroxyl radicals ( $OH^\bullet$ ) and ions ( $OH^-$ ).

Subsequently, oxidative stress ( $OH^\bullet$ ) and iron overload cause plasma membrane phospholipid peroxidation (PL-OOH), mainly polyunsaturated fatty acids (PUFA) and ferroptosis, a non-apoptotic cell death mechanism by iron overloading and lipid peroxidation due to a decrease in the GPX4 activity. GPX4 is the sole enzyme that detoxifies PL-OOH using two GSH.

In addition, arachidonate 5-lipoxygenase (ALOX5) and 12/15ALOX, which are regulated by iron and oxidative stress, may also be activated and mediate PL-OOH.

Ferroptosis, being a non-apoptotic cell death, releases cellular DAMPs (damage-associated molecular patterns) including oxidised mtDNA and nuclear HMGB1 (high mobility group box 1), which further evoke innate immune responses.

Further, LMP activates NLRP3 inflammasome. ALOX5 generates leukotriene B4 (LTB4), which attracts immune cells such as microglia/macrophage mediating neuroinflammation and neurodegeneration in DR. Therefore, we propose that gene therapy for TXNIP knockdown and/or administration of mitochondria-targeted antioxidants (mito-Tempo, SS31), iron chelating

agents (deferriroxo, deferiprone) and ALOX inhibitor (Zileuton) may serve as potential combination therapies to prevent/slow down the progression of DR.

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**WAYNE STATE**  
School of Medicine

**Lalit Singh Pukhrambam, PhD**  
**Associate Professor**

(Tenured) Department of Ophthalmology,  
Visual and Anatomical Sciences (OVAS),  
Wayne State University School of Medicine  
540 E Canfield, Scott Hall 8332  
Detroit, MI 48201, USA  
Tel: + 1 313 577 5032  
ak1157@wayne.edu  
www.anatomy.med.wayne.edu/profile/ak1157

# The National Stroke Programme for England: How to achieve world-class stroke care

Juliet Bouverie, Chief Executive of the Stroke Association, tells us how the NHS Long Term Plan and National Stroke Programme have the potential to transform stroke services across England in the next five years

This is an exciting time to be working in stroke. We know how to detect and manage the two main risk factors for stroke, there are real advances in stroke treatment and stroke research is starting to indicate some exciting breakthroughs. In England, there is a clear recognition now, from those in government and across the stroke community, that we must work together to tackle one of the biggest health challenges of our time. The NHS Long Term Plan and National Stroke Programme are vital to achieving this.

## NHS Long Term Plan and the National Stroke Programme

Stroke affects 1.2 million people across the UK and remains the fourth biggest killer and the largest cause of adult disability. Every five minutes, stroke destroys lives. And it turns the lives of carers and families upside down. This is why it is reassuring to see stroke included as a new clinical priority in the NHS Long Term Plan.

As well as saving half a million lives through improved CVD prevention, NHS England's plan promises to increase access to thrombolysis and thrombectomy treatments, to overhaul the stroke workforce and to transform rehabilitation models post-stroke. This is a big opportunity for us all. Collectively achieving these ambitions would help hundreds of thousands more people each year to rebuild their lives after stroke.

In partnership with NHS England and others, the Stroke Association has developed the National Stroke Programme for England, supporting the Long Term Plan's aims. As co-chair of the Stroke Programme Delivery Board, I'm encouraged to see work progressing across the five main priority areas – preventing strokes,

redesigning acute stroke services, improving rehabilitation and ongoing care, modernising the workforce and strengthening data and research.

## The vehicle for change: hyper-acute stroke units

Across England, we need to look at the very basic structure of stroke services. Do local stroke pathways actually make sense, provide quality care for all and integrate acute and post-acute services?

Here, the hyper-acute stroke unit (HASU) model of stroke services, taking patients to hyper-acute centres of excellence rather than the nearest hospital A&E department, is vital. Robust evidence shows us that this model is effective at saving lives, reducing the chance of disability and shortening the time spent in hospitals. This is why the Stroke Association fully supports efforts to reconfigure stroke services into HASUs.

In London and Manchester, reconfiguring services into the HASU model has saved an average of 100 and 70 extra lives per year respectively and Northumbria has seen significantly improved patient outcomes. Evidence shows that stroke patients treated in HASUs are more likely to survive and recover more quickly because these units are fully staffed and equipped and set up to deliver specialist and effective care 24/7. This also helps to address the significant workforce shortages and challenges in stroke by concentrating specialist stroke skills and expertise under one roof.

Yet across the country, public and political opposition often stands in the way of reconfiguring stroke services into HASU models, leading to patchy progress.





### Ending the 'postcode lottery' of stroke care

Standards of stroke care today vary enormously across the country, affecting your ability to survive and recover. It is simply not good enough that 45% of stroke survivors feel abandoned after they leave hospital and are not all able to access the rehabilitation and lifelong support that they need. Last month, another CQUIN was introduced, this time to increase the numbers of stroke survivors accessing vital six-month reviews. These will enable stroke survivors to access more personalised support and help to rebuild their lives after stroke.

Equity of access is key here. As James Green, who has lost three of his family members to stroke and now campaigns with the Stroke Association, explains:

"For me, the overriding priority for the new National Stroke Programme is reducing the postcode lottery of care for those who have had a stroke. We must have a level field for everyone no matter where you live or your wealth."

### Priorities for the future

NHS England's goals for stroke are rightly ambitious and they will require sustained effort and real leadership to drive through improvement. The next five years should be about translating good intentions into action. Together, we must make sure there are tangible improvements for stroke survivors and their carers. We need to be bold and accept where things are not working and design services so that everybody can access world-class stroke care. Stroke survivors deserve a better deal than they are getting today and I and others will continue to push for stroke to be the priority it needs to be. ■

#### Juliet Bouverie Chief Executive

Stroke Association  
Tel: +44 (0)300 3300 740  
supportercare@stroke.org.uk  
www.stroke.org.uk  
www.twitter.com/TheStrokeAssoc

Through the National Stroke Programme, work will also soon start to develop Integrated Stroke Delivery Networks (ISDNs) in all areas of England, bringing people and organisations together to create the best stroke pathway possible for local populations. Creating HASUs should be a top priority. It is proven to improve outcomes and we simply cannot afford to delay a process that will save lives.

### Accessing game-changing treatments

Currently, only 10% of eligible patients have access to mechanical thrombectomy, a game-changing clot-retrieval treatment that reduces the severity of the disability that a stroke can cause. In some cases, thrombectomy also saves lives.

We want all eligible patients to access this transformative treatment as soon as possible, regardless of where they live. Again, we will only make real progress here once we get the basics right – properly and efficiently organised stroke services in each region delivered round the clock and enough stroke specialists trained up to carry out these complex procedures. A new national commissioning goal (CQUIN) to encourage thrombectomy training will also help and I hope to see many local health systems taking advantage of this.

It is good to see the Long Term Plan recognises how effective thrombectomy can be and the potential cost-savings involved. On average, each patient treated with mechanical thrombectomy saves the NHS nearly £50,000 over just five years.

# Adaptive Robotic Gripper: The pathway to grasp the wave of Industrial 4.0 and smart manufacturing

Jen-Yuan (James) Chang, Professor at the Department of Power Mechanical Engineering at the National Tsing Hua University, Taiwan, tells us why the Adaptive Robotic Gripper is the route to grasp the wave of Industrial 4.0 and smart manufacturing

In Industry 4.0 applications, being able to hand and grasp objects of any shape precisely and reliably are essential in smart manufacturing operations. In this article, several essential considerations concerning the development of a robotic gripper are discussed and illustrated by an adaptive robotic gripper developed through research funded by Ministry of Science and Technology, Taiwan. Possibilities of such adaptive robotic gripper with artificial intelligence are discussed in the context of applications in smart manufacturing.

With the advancement of technologies and increasing demand for grasping objects automatically, robots have been widely used in industrial, commercial and even home applications. For applications in daily life and in the smart manufacturing environment, a robotic gripper, which could be used universally to grasp objects of any shape, has become its engineering importance. Featuring high accuracy, high repeatability and strong gripping force, an industrial robotic gripper which can be attached to a robot's end-effector is commonly designed to possess a single degree of freedom actuation, resulting in simple opening and closing operations. Although it has the aforementioned advantages, it is hard to adapt such design to dif-

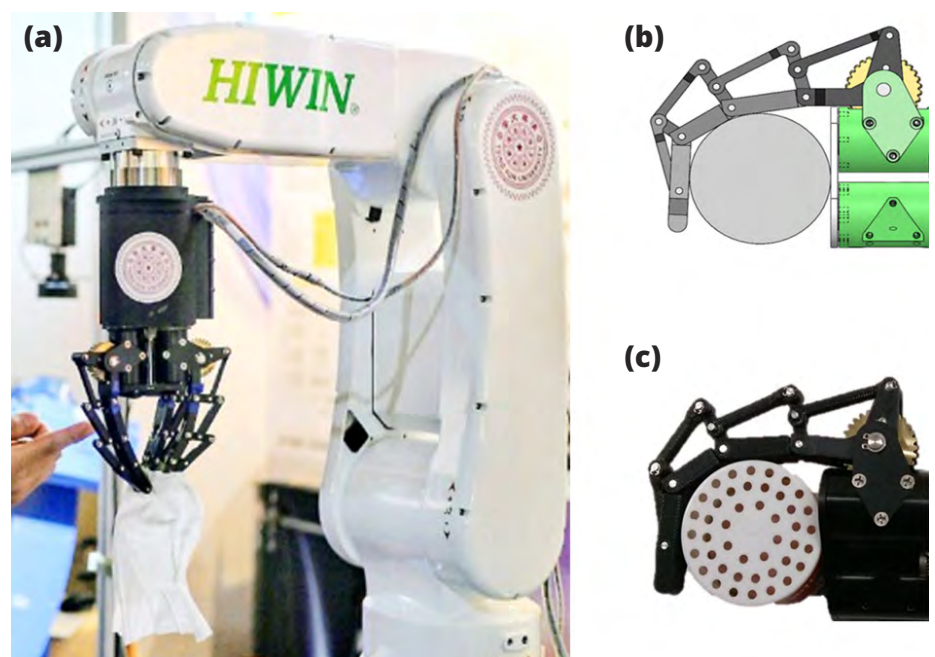


Figure 1. (a) The NTHU adaptive gripper installed on the robot arm pinching a tissue paper. This is an illustration of how the gripper's finger can adapt to the shape of the object (b) by simulation and (c) by experiment

ferent objects. In present practice with such an of actuation design, when a target object is changed, a different adaptor to suit for the object's shape is required. As such, to reach the flexibility of grasping, changing adaptor in this single degree of freedom gripper is necessary.

The most dexterous gripper currently available is the Human's Hand, which was demonstrated by researchers from Johns Hopkins University. To mimic the characteristics of a human

hand, a multiple degrees of freedom humanoid robotic hand has been widely researched with efforts placed on the minimisation of actuators, such as motors (the mechanical structures in a limited space). Although its dexterity is satisfactory, the cost is extremely high and is not sufficiently compliant to adapt to a different shape. To offer compliance, some soft materials have been used in the robotic hands as well, the best example of which was demonstrated by researchers from Harvard University.

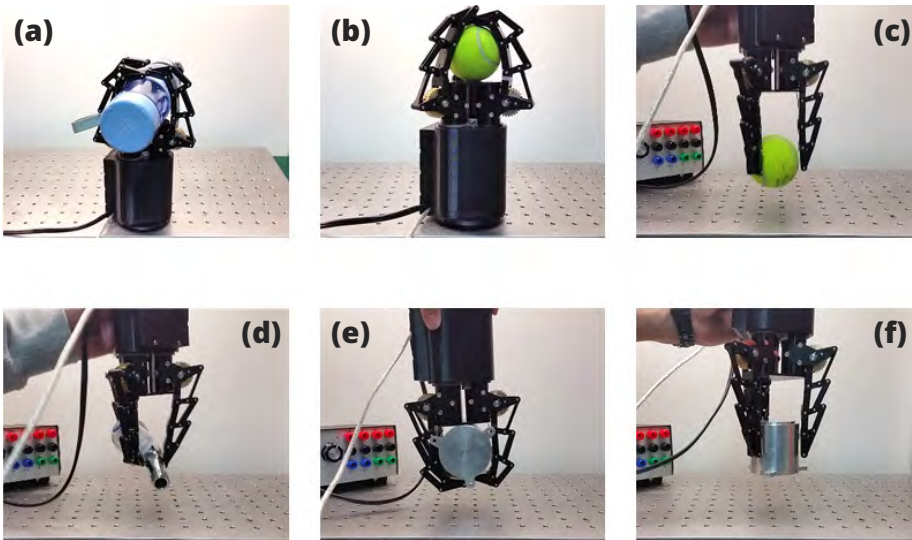


Figure 2. These photos show the adaptation of the NTHU Gripper in grasping (a) cylindrical bottle, (b) and (c) tennis ball, (d)-(f) hardware with irregular shapes

Although a soft gripper can offer good compliance and adaption to shapes, its accuracy and payload, in fact, are very limited due to soft materials.

**“With the advancement of technologies and increasing demand for grasping objects automatically, robots have been widely used in industrial, commercial and even home applications.”**

To reduce the driving sources, such as the number of motors used but to keep or even improve the adaptability of the gripper, the adaptive robotic gripper as shown in Figure 1 has been developed by Professor Chang's research group from the Department of Power Mechanical Engineering at National Tsing Hua University, Taiwan. Through funding support from the Ministry of Science and Technology, Taiwan, the research results were technology transferred to HIWIN Technologies Corp. for the development of commercial adaptive grippers that can be used in smart manufacturing applications. As illustrated in Figure 1(b) and Figure 1(c), the so-called compliance or adaptation can be achieved by the multiple four-bar linkages packed in series. Each linkage can be

assumed to be rigid to be able to transmit a strong gripping force to grasp an object. With the well-engineered design of the mechanism of the four-bar linkages in series, adaptation and compliance can be achieved. Based on the four-bar linkage in the series design concept, Professor Chang's group have developed mathematical functions for each adaptive gripper finger joint to allow the development of adaptive robotic gripper for different service and industrial robotic applications. With the analytical model and mechatronics integration, the fingers of this NTHU adaptive gripper not only offer compliance and adaptation performance similar to the human finger but they also provide satisfactory engineering performance in terms of receptivity and reliability. The NTHU adaptive gripper offers a wide range of payload performance. It can easily lift up and hold a 3 kg object, as well as to pinch a piece of tissue paper, as illustrated in Figure 1(a).

Mimicking the human hand in which dexterity is achieved primarily by the thumb, the index and the middle fingers with the ring finger and little

finger are pretty much used to help hold objects. Certainly, three fingers designed with the series four-bar linkages are adopted in this NTHU adaptive gripper to save on the cost but also offer the same performance and dexterity. Each finger is placed evenly by 120 degrees and is attached to the controller unit of the gripper. However, the adaptation of the gripper is further extended by allowing each finger to rotate independently at desired orientations. As demonstrated in Figure 2, the orientation of the gripper finger can be adjusted according to the shape of the object. Such adaptation is not possible in the present robot gripper, which certainly offers the possibility of eliminating a change of adaptor in the present industrial robotic gripper. Should such a dexterous adaptive robotic gripper be integrated with the machine vision, machine learning and artificial intelligence (AI), the intelligent grasping operation can truly be achieved in smart manufacturing, as well as in Industry 4.0 applications.



**Jen-Yuan (James) Chang**  
Professor

Department of Power Mechanical Engineering  
National Tsing Hua University, Taiwan  
Tel: +886 3 574 2498  
jychang@pme.nthu.edu.tw  
<http://www.pme.nthu.edu.tw/files/14-1265-74003,r4027-1.php?Lang=en>



# The burden of viral hepatitis in the WHO Region of Africa

Ahead of World Hepatitis Day on 28th July 2019, the WHO Regional Office for Africa detail the key issues when it comes to the burden of viral hepatitis in the WHO Region of Africa

As many as 325 million people around the world are affected by the global epidemic of hepatitis B and C – more than ten times the 36.7 million people who are living with HIV.<sup>1</sup> Sub-Saharan Africa has one of the highest burdens of disease with over 60 million living with chronic hepatitis B, 4.8 million of whom are children younger than five years old. The regional prevalence of hepatitis B (HBV) infection is about 6.1%, with approximately one in every 15 people (1:15) infected. Additionally, there are 10 million living with chronic hepatitis C infection (HCV), with a prevalence of less than 1% infected (i.e. one person in every 100).

Viral hepatitis affects adults, adolescents and children in this region and also occurs as a co-infection in people with non-communicable and communicable diseases. Among people living with HIV globally, 4 million people have HIV-hepatitis co-infection. Undetected and untreated, these patients are also at risk for liver disease undermining the gains of the HIV response. In Africa, HBV is predominantly transmitted in the perinatal and childhood period and from mother to child; whilst unsafe injection practices both in health facilities and community account for the majority of hepatitis C infection. Intravenous drug use is an emerging concern for HCV transmission in Africa.

According to the most recent estimates of the Global Burden of Disease,<sup>2</sup> viral hepatitis was responsible for approximately 1.5 million deaths in 2015. Every day, more than 3,600 people die of viral hepatitis-related liver disease, liver failure and liver cancer. The death rate from hepatitis B and C has increased by 22% in 2015 from the baseline in 2000. The available evidence suggests that over 2 million Africans with chronic HBV and HCV may develop progressive liver disease in the next few decades if no intervention is deployed. Viral hepatitis mortality is becoming a bigger global threat

than death from HIV/AIDS (1.3 million), malaria and tuberculosis (TB) [0.9 million and 1.3 million, respectively].

It is clear that viral hepatitis has become an emergency. The availability of highly effective generic antiviral therapy for hepatitis B that cost \$30 a year and the rapidly declining cost of generic curative HCV medication make universal access to viral hepatitis screening and treatment feasible. The benefits of hepatitis elimination beyond health outcomes include averted medical costs and reduced time spent in sickness. These savings accrue to improvement in education, economic growth and in accelerating poverty reduction in families' communities and nations.

A coordinated public health response in Africa is needed. Government leadership and community collaboration are pivotal to providing an enabling environment for collaboration and partnership in addition to mobilising funding, training and the successful implementation of a country-specific hepatitis response.

## The African Response to the Global Health Sector Strategy for Viral Hepatitis and

The WHO Global Health Sector Strategy (GHSS) for viral hepatitis elimination was endorsed by the WHO Member States during the 2016 World Health Assembly (WHA 69.22). The strategy set ambitious targets for elimination of viral hepatitis as a public health threat by 2030 and promotes universal access to hepatitis preventive, screening and treatment services (see table 1). It also promotes synergies between viral hepatitis and other health issues and positions the viral hepatitis response within the context of universal health coverage.<sup>3</sup>

The African Regional Framework for hepatitis Prevention, Care and Treatment (2016-2020), guides the WHO

The World Health Assembly pledged to reach elimination				
5 core interventions with sufficient coverage would lead to elimination (incidence -90%, mortality -65%)				
Interventions	Indicator	2015	2020	2030
3 dose HBV vaccine	Coverage	84%	90%	90%
HBV PMTCT	Coverage	39%	50%	90%
Blood / injection safety	Screened donations	97%	100%	100 %
	Safe injections	95%	100%	100%
Harm reduction	Sets/PWID/year	27	200	300
HBV and HCV testing and treatment	% diagnosed	9/20%	30%	90%
	% treated	8/7%	N/A	80%

three countries are implementing a government-led public health approach and making significant progress towards the GHSS 2020 and 2030 target. Some of the significant barriers to mounting an effective African response to viral hepatitis include poor community and political awareness, inadequate data for decision making and advocacy, limited access to affordable diagnostics and drugs and inadequate financing and lack of trained health workforce. This [scorecard](#) takes a closer look at the progress of countries in Africa towards these targets.

Member States to implement the Global Health Sector strategy on viral hepatitis (2016-2021) and proposes priority actions such as developing evidence-based and costed national plans, strengthening hepatitis prevention and developing strong and funded hepatitis screening and treatment programmes.<sup>4</sup> The national hepatitis response should be guided by a national plan with a clearly defined governance and management structure that can ensure a coordinated and efficient response and clear accountability.

In the Africa region, the hepatitis response is lagging behind other all other regions. The [scorecard](#) summarises some of the progress made in implementing the core priorities for Africa. Currently, 27 countries have developed a national action plan for viral hepatitis, but only 13 countries (30%) have officially endorsed and launched it. Strong progress has been made in hepatitis prevention, but coverage of timely hepatitis B birth dose is only 10%. As shown in the [scorecard](#) only 11 countries have established timely hepatitis birth dose for the control of perinatal and mother-to-child infection (see #3 in the [scorecard](#)).

Screening and treatment programme to identify the 71 million Africans with chronic infection are vital to reduce the morbidity and mortality of viral hepatitis and reaching the WHO impact targets. Of the 30 highest burden countries, only eight have established screening and treatment programmes most of which are small scale implementation projects in specialist centres. Despite the availability of highly effective generic antiviral therapy for hepatitis B and C, only

Since 2015, the WHO Regional Office for Africa has also contributed to advancing the regional hepatitis response with the ultimate goal to save the lives of 6 million people living with viral hepatitis in the region by 2030. Some of the achievements to date include providing support tailored to the needs of individual countries and includes promoting the development of evidence-based national action plans aligned to country characteristics, development of normative guidance and treatment guidelines and coordinating hepatitis surveillance and data to facilitate regional and global hepatitis reporting. WHO is also promoting regional awareness by supporting national commemorations of World Hepatitis Day (July 28), capacity building and high-level meetings such as the African Hepatitis Summit. ■

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## Prof. Olufunmilayo Lesi

Regional Medical Officer for Viral Hepatitis

WHO Regional Office for Africa

Tel: +(47 241) 39975

lesio@who.int

[www.afro.who.int](http://www.afro.who.int)

[www.twitter.com/WHOAFRO](https://twitter.com/WHOAFRO)

# Enhancing One Health surveillance systems

Researchers from SACIDS Foundation for One Health discuss the importance and implementation of event-based community surveillance using a One Health approaches in East and Southern Africa

The Sokoine University of Agriculture in collaboration with the National Institute for Medical Research through the SACIDS Foundation for One Health has developed and deployed a digital technology branded AfyaData to enhance community-based disease outbreak early detection and prompt response in East and Southern Africa. This work, funded by the Ending Pandemics, is led by the One Health Sciences Community of Practice (OHS CoP) Coordinator, Professor Esron Daniel Karimuribo. The CoP operates under four pillars namely: One Health surveillance systems; Ecosystem Health; One Health Policy; and Agri-Health systems.

The growing body of evidence shows that about three-quarters of human infectious diseases have an animal origin. This observation suggests that One Health approach is considered to be the most effective strategy for managing infectious diseases and the associated risks. Scanning through the event-based surveillance systems in human and animal health sectors in Tanzania, we learnt that the systems faced some challenges including inadequate engagement of community, untimely capturing and submission of reports on health events from the primary sources, lack of feedback loops, difficulty in contact tracing and intra- and inter-country inadequate inter-sectoral information sharing. We have observed that disease outbreaks typically erupt at a

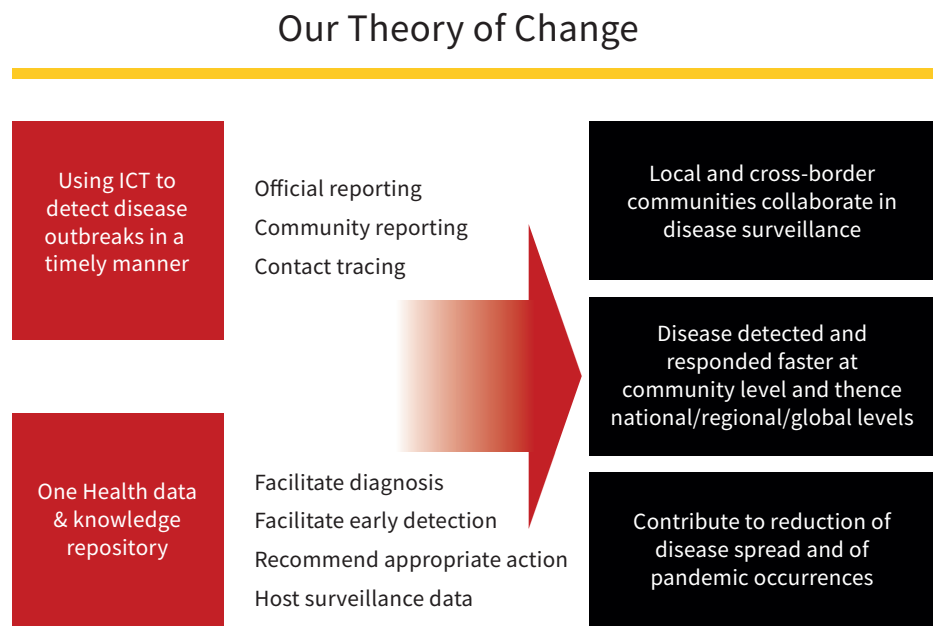


Figure 1: SACIDS theory of change's diagram

community level and hypothesised that community-based participatory disease surveillance could enhance early detection, timely reporting and prompt control. Furthermore, we have realised that most vulnerable communities are located in hard to reach areas with poor infrastructure, which motivated us to think about the fit-for-purpose innovative approaches to strengthen event-based surveillance (EBS) in Tanzania and beyond.

## Our approach

Participatory event-based surveillance (EBS) is driven by our theory of change summarised in figure 1, to work across human and animal health sectors to fight disease epidemics, to develop ICT tools to support data capture, reporting and feedback at health facil-

ity and within the community (feed into the official national human and animal health information systems), and to strengthen cross border collaboration to fight epidemics in shared ecosystems. We seek to link the EBS data from community to district, regional (provincial), national and global scales.

## About AfyaData

AfyaData is an open source digital disease surveillance tool that eases the collection, analysis, documentation and feedback of public/animal health events. It is a set of two applications – a mobile Android based client and a web-based application acting as a server. The mobile client is used for collecting and submitting surveillance data, and receiving and/or tracking





## • Basic Configuration

A = Strictly Human Diseases

B = Strictly Animal Diseases

C = Shared Diseases = Zoonoses

D = Specific Disease active surveillance/vertical system

• Configuration for Public Health = A + C

• Configuration for Animal Health = B + C

• Active specified human disease = D

• Active specified animal disease = D

[www.sacids.org](http://www.sacids.org)

feedback from various levels. The server component caters for data storing/hosting and management.

### How it was designed

AfyaData was designed in 2010 as a collaborative partnership between SACIDS and ministries responsible for human and animal health in Tanzania. Collaborative designing was extended to regional animal and human health epidemiologists, Information, Communication and Technology (ICT) specialists and community representatives through EpiHack event convened in Arusha, in December 2014, which was attended by 66 specialists (medical, veterinary and ICT programmers) from 14 countries.

### Basic configuration of AfyaData

Its basic configuration comprises four strands namely (a) strictly human diseases, (b) strictly animal diseases, (c) diseases transmissible between animals and humans (zoonoses), and (d) specific disease active surveillance/vertical system.

### How it functions

AfyaData toolset has the capability to manage entire data collection lifecycle, from managing users, loading forms, collecting data in the field, sending collected data to a server, and viewing data on the server and providing feedback to data collectors and/or persons of interest. The app is designed to collect georeferenced data online or offline in locations without internet and data can be submitted later when one is at a location with internet. It supports prompt analysis, visualisation and presentation of data in different formats including graphs and maps. Its dashboard provides a quick overview and reflections of the programme trend/achievement in intervention strategies/measures. It can integrate data from multiple sources and is enhanced with an early warning short message service for notification to decision makers on health events through their mobile phones.

AfyaData is powered by One Health Knowledge Repository (OHKR), which

is a decision-making system with expert-authored content that helps to support the prediction of likely disease conditions based on the reported signs and symptoms. It can be used for sample tracking and communication of test results between different points/sections of the health care delivery system using barcode feature. It supports multiple languages and can be customised based on different clients' needs including language, surveillance, data integration needs.

### AfyaData deployment strategy

Prior to its deployment in the selected areas, consultative meetings were held with ministries responsible for human and animal health and the President's Office Regional Administration and Local Government in Tanzania to identify the specific needs and agree on the areas and deployment strategy. From the national level, we the consulted district officials responsible for human and animal disease surveillance and draw up the

specific area deployment strategy based on the identified local needs. The local leaders and officials working in human and animal health sectors at the community level were actively engaged in the identification and recruitment of Community Health Reporters (CHRs) who were subsequently trained on the use of AfyaData in EBS.

## Scope of AfyaData deployment

Between March 2017 and December 2018, the focus has been on the rolling out of AfyaData using One Health disease surveillance model to support capture of health events in human and animal populations and their environment at a community level in selected areas. So far the rolling out has been completed in Kilosa, Malinyi, Ulanga, Ngara and Wete districts of Tanzania. During the period AfyaData was used to enhance capture of cholera suggestive cases and environmental risk factors, as well as sharing of laboratory results between different points/sections of the health care delivery system. This was implemented using a specific cholera surveillance model in selected areas, which included Morogoro Urban, Mvomero, Kilosa, Kinondoni and Temeke districts of Tanzania.

Afyadata has been used to support official animal disease surveillance in selected areas in Tanzania. It has been used to collect information of the health status of animals at slaughter houses/premises in selected areas.

There are currently over 460 users of AfyaData at community level in Tanzania. Moreover, AfyaData has been used to collect baseline data on the functionalities of event-based surveillance in the communities of selected cross-border ecosystems in

East Africa to inform the strengthening strategies between the countries. Within the next 18 months we plan to roll out AfyaData to others areas of Tanzania and neighbouring countries to enhance linkage of health events from community to the formal disease surveillance systems.

AfyaData has been introduced to the Ministry of Health of the Democratic Republic of Congo to support surveillance of Ebola Virus Disease (EVD). The training of trainers and the digitization of various surveillance forms to be used in EVD monitoring and evaluation have been conducted. Plan is in place to deploy AfyaData at community level and other potential levels in DRC.

We have initiated collaboration with the Food and Agriculture of the United Nations (FAO) and Ministry of Livestock and Fisheries in Tanzania to link data being collected from community level using AfyaData with EMA-I (an FAO disease surveillance tool deployed at district level). This collaboration strategy heightens the linkage of health events from community level to global level. In addition, we have successfully put up a proposal to support Africa CDC surveillance; an initiative that will enhance event-based surveillance in 55 Africa CDC member countries.

## Data access

The collected data are strictly kept confidential and accessed near to real-time and owned by the relevant authorities (Ministries of Health, Livestock and Local Government Authority and others as defined by the relevant authority) through specific access code. AfyaData enhances linkage of human and animal health events from community level to district, national, regional and global levels.

Authors and affiliation: By Professor Esron D. Karimuribo, Dr. Calvin Sindato, Dr. Leonard E.G. Mboera and Eng. Eric Beda. The SACIDS Foundation for One Health, Sokoine University of Agriculture, Tanzania.

"SACIDS Foundation for One Health" against "Southern African Centre for Infectious Disease Surveillance (SACIDS) Secretariat".



**Professor Esron D. Karimuribo**  
**Coordinator**  
One Health Sciences Community of Practice

**Dr. Calvin Sindato**  
**One Health Epidemiologist**

**Dr Leonard E.G. Mboera**  
**Coordinator**  
Emerging and Vector-Borne Disease  
Community of Practice

**Eng. Eric Beda**  
**Regional ICT Specialist**  
Sokoine University of Agriculture  
P.O. Box 3297, Chuo Kikuu, MOROGORO,  
Tanzania  
secretariat@sacids.org  
www.sacids.org



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# Infection prevention: Overcoming challenges in sepsis diagnosis

Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group discusses the concerns with overcoming challenges in sepsis diagnosis

Sepsis is a rapidly progressing, life-threatening inflammatory syndrome that occurs as a result of a local infection leading to the systemic disruption of the host's immune responses and coagulation reactions. According to the World Health Organization (WHO), which declared sepsis a global health priority, more than 30 million people worldwide every year develop sepsis syndrome, which potentially leads to 6 million deaths (WHO Fact Sheet, 2018). Low- and middle-income countries account around 3 million newborns and 1.2 million children suffering from sepsis every year (WHO Report, 2017).

Factors influencing the extent of inflammation are significantly heterogeneous. The site and cause of initial infection and the timing of support administration constitute the most relevant aspects to take into consideration. Therefore, most clinical trials attempting to target specific signaling pathways disrupted by sepsis fail. Indeed, no specific therapeutic options are available at present days (Leligdowicz and Matthay, 2019).

Regarding diagnostics, different individuals mostly exhibit immune paralysis, endothelial injury and multi-organ failure, as the most frequently observed aspects. Nevertheless, the underlying mechanisms responsible for these signs are still poorly understood. Consequently, clinical verdict is based on comprehensive physiological parameters and time consuming lab-based cell culture. These facts constitute critical issues for a condition that can severely increase over a short period of time.

The development of innovative methods for sepsis recognition and compliance with treatment urgency represent an increasing concern among the clinical community. According to the experts, the challenge relies on the subjectivity of sepsis related to the

absence of a pathological gold standard. However, the implementation of administrative codes to track sepsis, including screening and retrospective audits, may increase the likelihood evidence sepsis cases at an early stage, hence helping to diminish sepsis mortality rates (Rhee et al., 2019).

## Opportunities and solutions

Because of the high risk of death associated with uncontrolled sepsis, the development of a new point of care testing (PoCT) tools for sepsis may constitute a remarkable solution. PoCT devices could not only increment diagnostic speed and accuracy but also provide timely administration of best-fit therapeutics (Oeschger et al., 2019). This strategy would significantly reduce risks while enhancing patient outcomes. The healthcare burden would be drastically diminished as well.

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*“According to the World Health Organization (WHO), which declared sepsis a global health priority, more than 30 million people worldwide every year develop sepsis syndrome, which potentially leads to 6 million deaths (WHO Fact Sheet, 2018). Low- and middle-income countries account around 3 million newborns and 1.2 million children suffering from sepsis every year (WHO Report, 2017).”*

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Similarly, hospitals and care centres are beginning to use of machine learning algorithms on continuous streams of physiological data with the purpose to early identify patients in risk of developing sepsis with high accuracy in real-time (van Wyk et al., 2019). The risk of sepsis (RoS) score was developed based on the systemic inflammatory response syndrome (SIRS) and the sequential organ failure assessment (SOFA), among other standards (Delahanty et al., 2019), with the aim

to provide a more opportune and reliable tool than single benchmark screening tools.

Smart healthcare solutions such as PoCT devices and machine learning algorithms enable data to be analysed, visualised and shared in real time; thus, significantly improving clinical outcomes (Van Cauwenberghe, 2016).

**“Because of the high risk of death associated with uncontrolled sepsis, the development of a new point of care testing (PoCT) tools for sepsis may constitute a remarkable solution. PoCT devices could not only increment diagnostic speed and accuracy but also provide timely administration of best-fit therapeutics (Oeschger et al., 2019).”**

## Final remarks

Host disease presentation defines the course of treatment in sepsis. The inherent heterogeneity associated with this condition remains a critical concern to promptly dispense immunosuppressive or immune-augmenting therapies. Best efforts are associated with early stage, on-site diagnosis, as well as, the implementation of machine learning methods for risk scoring. A long road is still left to achieve definitive solutions for sepsis treatment. ■

## Acknowledgements

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**Cecilia Van Cauwenberghe, PhD, MSc, BA**  
**Associate Fellow and Senior Industry Analyst**  
 TechVision Group, Frost & Sullivan  
 cecilia.vancauwenberghe@frost.com  
 ww2.frost.com  
 www.twitter.com/Frost\_Sullivan

# Hand hygiene helps reduce HCAs

Chris Wakefield, Vice President at GOJO Industries-Europe Ltd, highlights how hand hygiene systems benefit public health by reducing the spread of healthcare associated infection (HCAI)

It is estimated that 300,000 patients a year in England acquire a healthcare associated infection (HCAI) as a result of care within the NHS. Such infections draw large attention from patients, regulatory bodies and the media. Not only because of the magnitude of the problem – after all, they are associated with morbidity, mortality and the financial cost of treatment – but, also, because most are preventable.

Despite being avoidable, HCAs continue to present a major threat to our public health. They are particularly difficult to eliminate due to the speed and ease that they can be transmitted – and because of their long-life span. Did you know, for example, that MRSA can live up to nine weeks, whilst *C. Diff* spores can live up to five months? Or that they can be spread through both direct and indirect contact?

Studies have shown that contaminated hands can sequentially transfer some viruses to up to seven surfaces, and that fourteen people can be contaminated by touching the same object one after the other. Perhaps it's not surprising then, that research indicates that you have a 50/50 chance of picking up a dangerous pathogen anytime you touch anything or anyone in a hospital.

Such outbreaks can have serious repercussions; including the increased risk to the lives of vulnerable patients, disruption of services and reduced clinical activity, such as the enforced

closure of hospital wards, cancelled admissions and delayed discharges. There is also the cost of treatment to factor.

Indeed, a report by the National Audit Office estimated that a reduction in the rates of MRSA bloodstream infections saved the NHS in England between £45 million-£59 million in treatment costs between 2003/4 and 2008/9. It also identified that by reducing the rate of *C. difficile* infections, between £97 million-£204 million was saved in treatment costs between 2006/7 and 2007/8.

## Going back to basics

A great deal of scientific research has shown that, if properly implemented, hand hygiene is the single most important, easiest and cost-effective means of reducing the prevalence of HCAs and the spread of antimicrobial resistance. In fact, research shows it can cut the number of HCAI cases by up to 50%. Several other studies have also demonstrated that handwashing virtually eradicates the carriage of MRSA which invariably occurs on the hands of healthcare professionals working in intensive care units. An increase in handwashing adherence has also been found to be accompanied by a fall in MRSA rates.

In order to reduce the spread of illness, everyone has to engage with hand hygiene practices – not only healthcare workers, who already

make this a part of their daily lives, but visitors and patients too. As a founder member of the World Health Organization (WHO) Private Organizations for Patient Safety group, GOJO is a strong advocate of the 'total solution' approach to making hand hygiene second nature to everyone in a healthcare setting. We believe that, to successfully change behaviour, a triple-pronged approach is required.

Firstly, handwashing facilities must be accessible and dispensers easy to use. The WHO recommends that an adequate number of appropriately positioned hand hygiene facilities should be readily available at the point of care.

Secondly, the high frequency with which healthcare workers clean their hands means that the formulations must be gentle yet effective against germs, complying with key hospital norms EN 1500, EN 14476 and EN 12791. Studies have also shown that using an alcohol-based hand sanitising rub can improve hand hygiene practice, since it is quicker, is microbiologically more effective and is less irritating to skin than traditional hand washing with soap and water.

Finally, eye-catching signage is very effective as a prompt, especially at key germ hot-spots such as washrooms and waiting areas. Hand hygiene facilities must remain well-stocked and maintained at all times too.





## Getting smart

Although evidence supports a 'back to basics' approach, digital innovation also has a role to play. GOJO has spent many years developing advanced formulations and high-tech dispensers, and has recently harnessed revolutionary smart technology to create its SMARTLINK™ Electronic Monitoring Solutions. These two mobile apps are a smarter way to help reduce the maintenance time spent on dispensers, and measure hand hygiene performance – ultimately helping to prevent the spread of germs.

Combining the latest technology with the simple act of hand hygiene, and working together to put effective systems in place, we can reduce the spread of HCAs. GOJO, the leading global producer of skin health and hygiene solutions for away-from-home settings, is your specialist partner in healthcare hygiene.

*For a tailored, effective, total solution for your setting, or for more information, please call +44 (0)1908 588444, email [infouk@GOJO.com](mailto:infouk@GOJO.com) or visit [www.GOJO.com](http://www.GOJO.com)*

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**Kerrie Doughty**  
**Trade Marketing & Communications Manager**  
 GOJO Industries-Europe  
 Tel: +44 (0)1908588457  
[infouk@gojo.com](mailto:infouk@gojo.com)  
[www.GOJO.com](http://www.GOJO.com)  
[www.twitter.com/GOJO\\_Hcare](https://www.twitter.com/GOJO_Hcare)  
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# Cardiovascular disease: Opportunities and challenges in the digital health era

In this interview, Chair of the ESC Digital Health Committee, Professor Martin Cowie, details the opportunities and challenges in the digital health era when it comes to the field of cardiovascular disease

Digital technology and the many ways it will impact the prevention, care and treatment of cardiovascular disease will be the subject of the first-ever dedicated digital summit to be organised by the European Society of Cardiology (ESC). The ESC brings together 95,000 members across 57 National Cardiac Societies. ESC Digital Summit will be held in Tallinn, Estonia on 5-6 October 2019.

“The summit will bring together those interested in digital health and technology to discuss the key issues, debate the challenges and opportunities and consider the roadmap to the future of the digital transformation,” says Dr Martin Cowie, Professor of Cardiology (Health Services Research) and an Honorary Consultant Cardiologist at the Royal Brompton and Harefield NHS Foundation Trust. Prof Cowie chairs ESC’s Digital Health Committee.

The summit and its focus on cardiovascular disease (CVD) could not be timelier. According to the World Health Organization (WHO), CVD has been the leading cause of death globally for the last 15 years.<sup>(1)</sup> The European Commission reports that over 10,000 patients in Europe die every day from CVD, far exceeding the number of deaths from cancer.<sup>(2)</sup> CVD is expected to remain the leading cause of death, premature death and the primary disease burden in Europe for the next two decades.

Some 1,000 stakeholders are expected to attend the summit. They will include cardiologists and other healthcare professionals, policymakers, academics interested in cardiovascular health and care, patient advocates, entrepreneurs, digital developers, representatives of finance and insurance companies and experts from the life-sciences industry.

An ESC survey of 2,100 members revealed that eight out of 10 healthcare professionals believe digital health will radically impact clinical practice while 94% of healthcare professionals say they need to learn more about digital health. Participants at the summit will share ideas on how advances in technology can be safely and wisely applied to cardiology.

The advent of technologies, including wearables, wireless mobile devices, artificial intelligence, big data, electronic medical records and social media will prompt changes impacting many aspects of the doctor/patient relationship. The effects so far look promising.

“The technology developments help support innovation, better outcomes for patients, more efficient and effective care and hopefully at a lower cost to ensure the sustainability of health and healthcare”, says Prof Cowie. “The changes can also enable clinical decision-making to be shared more with patients and help a non-specialist make decisions much like those made by a specialist. In other words, the ‘democratization’ of healthcare.”

Prof Cowie points out that for innovation to work, its value to patients and doctors must be clear. “It’s not as simple as taking a technology off the shelf and popping it into health care and seeing the result. If we use a new drug or we use a new device, we want really strong evidence of its effectiveness; we also want that for electronic technologies. There are two questions to ask; will it make a meaningful difference? And is that difference really worth the money? So it’s quite a challenging equation for technology.”

One issue certain to be discussed at the summit is concern about information security and patient privacy.

**“The advent of technologies, including wearables, wireless mobile devices, artificial intelligence, big data, electronic medical records and social media will prompt changes impacting many aspects of the doctor/patient relationship. The effects so far look promising.”**



“We are all aware of the recent data scandals and everyone needs assurance that the risk of data being used inappropriately is minimised,” says Prof Cowie.

**“According to the World Health Organization (WHO), CVD has been the leading cause of death globally for the last 15 years. (1) The European Commission reports that over 10,000 patients in Europe die every day from CVD, far exceeding the number of deaths from cancer. (2) CVD is expected to remain the leading cause of death, premature death and the primary disease burden in Europe for the next two decades.”**

Advances in combating CVD using digital technology are now being realised. Remote monitoring of implantable devices, such as defibrillators is already routine in many countries and allows earlier detection of any problems and more convenience for patients. Artificial intelligence (AI) interpretation of images also has begun to show benefit in terms of ensuring abnormal scans are identified earlier. Decision support

software provides doctors and patients access to best current evidence and the relevant options.

“This is only the tip of the iceberg and the next decade will see unprecedented changes in healthcare delivery and disease prevention using more digital technologies,” concludes Prof Cowie. ■

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**Professor Martin Cowie**  
**Chair of the ESC Digital Health Committee**

European Society of Cardiology  
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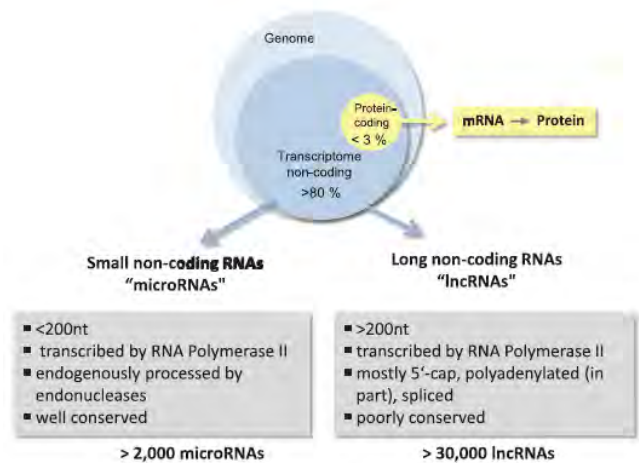
# Epigenetic: Revolutionary impact on medicine

Epigenetic is a novel and promising field of research that might have a revolutionary impact on medicine. Epigenetic is the study of heritable phenotype changes that do not involve alterations in the DNA sequence. Epigenetics is involved in changes that affect gene activity and expression, but is also used to in case of heritable phenotypic change, that may have effects on physiological or phenotypic traits. The standard definition of epigenetics is based on heritable alterations, either in the progeny of cells or of organisms.

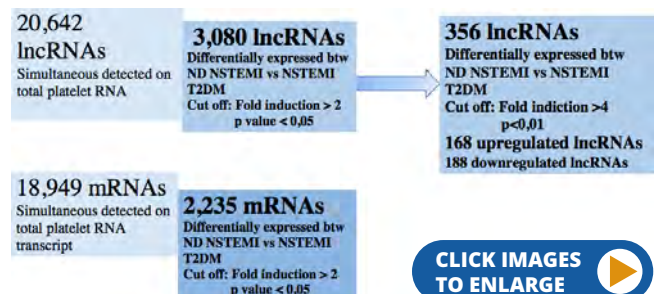
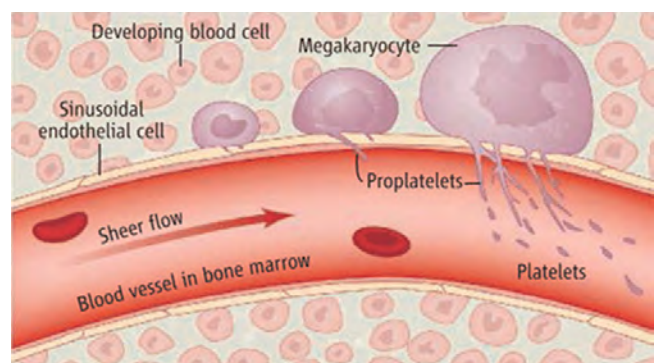
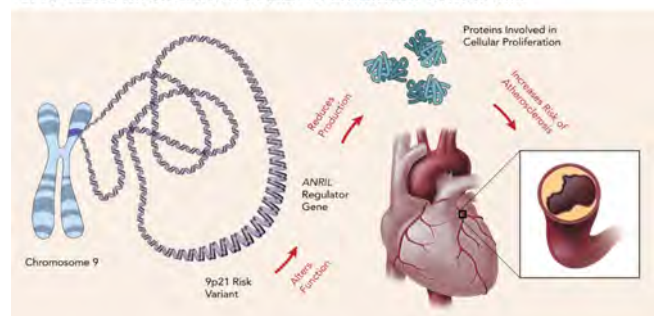
Differences among lncRNAs and micro.rna detected and those that are differentially expressed in non STEMI patients with and without diabetes.

This preliminary data may open the way to novel and potentially revolutionary treatment but requires more evidence.





#### EPIGENETIC MODULATION IN ACUTE CORONARY SYNDROME



Luigi Marzio Biasucci MD  
 Associate Professor of Cardiology  
 Fondazione Policlinico Universitario A Gemelli  
 Department of Cardiovascular and Thoracic Science  
 luigimarzio.biasucci@unicatt.it  
[http://docenti.unicatt.it/web/didattica.do?cod\\_do-cente=46359&language=ITA&section=didattica](http://docenti.unicatt.it/web/didattica.do?cod_do-cente=46359&language=ITA&section=didattica)

# The cardiovascular disease burden from ambient air pollution in Europe

Thomas Münzel MD, Andreas Daiber PhD, Ulrich Pöschl PhD and Jos Lelieveld PhD discuss the link between air pollution and cardiovascular disease in Europe

By way of an introduction, ambient and household air (indoor air) pollution are considered to be major health risk factors leading to morbidity and premature mortality with significant direct and indirect costs to the community<sup>1</sup>. The World Health Organization (WHO)<sup>2</sup> and the Global Burden of Disease (GBD) project<sup>1</sup> calculated for 2015, 4.2 million premature deaths per year worldwide due to air pollution especially by particulate matter with an aerodynamic diameter  $< 2.5 \mu\text{m}$  ( $\text{PM}_{2.5}$ ). More than half of the deaths were the result of cardiovascular diseases such as coronary heart disease and cerebrovascular disease due to embolic and hemorrhagic stroke but also due to other non-communicable diseases such as arterial hypertension, diabetes, lung cancer and chronic obstructive pulmonary disease.

## Death rates due to air pollution are significantly higher than previously thought

In 2018 and 2019, two new studies calculated a much higher mortality and morbidity burden than previously thought, in particular due to the use of a new and much more accurate hazard ratio function of the  $\text{PM}_{2.5}$  concentration-response association, the GEMM.<sup>3,4</sup> This model has a number of advantages over the Integrated Exposure-Response Function (IER) formerly used by the WHO and GBD and is now considered by both WHO and GBD to

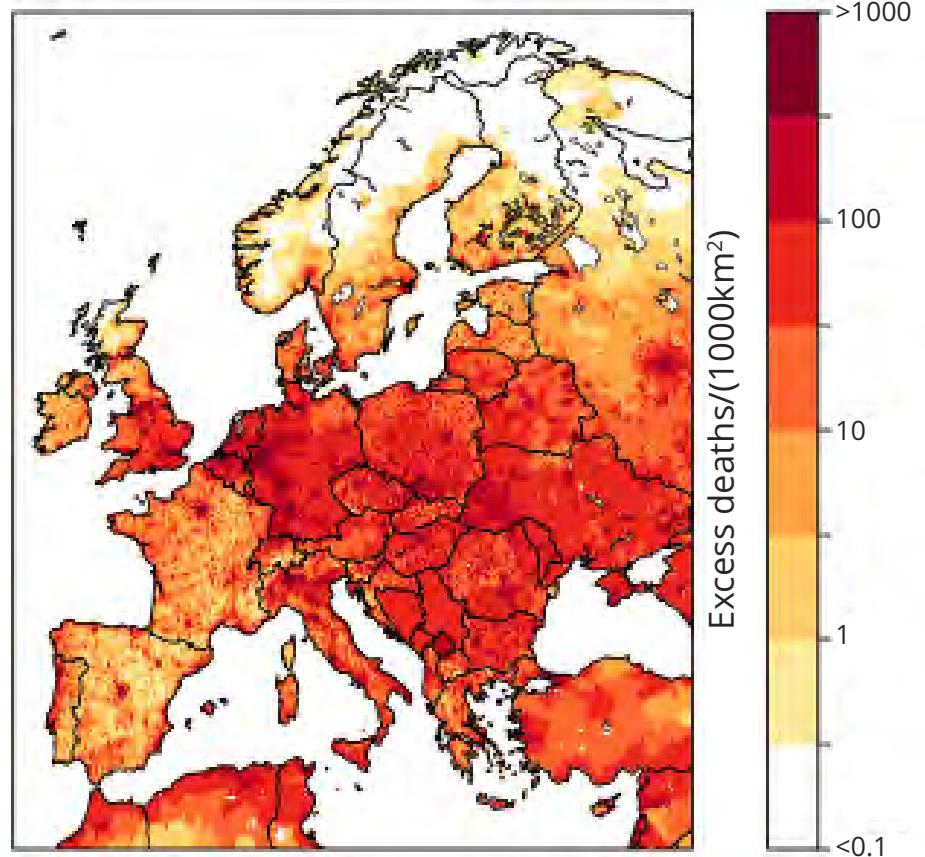


Figure 1. Regional distribution of estimated annual excess mortality rates from cardiovascular diseases (CVD = IHD (ischemic heart disease) + CEV (cerebrovascular disease) attributed to air pollution. These rates are lower limits as other non-communicable diseases are not included

Image: © 2019, Oxford University Press

calculate premature mortality. Richard Burnett's GEMM is based on the analysis of much larger and geographically extended epidemiological data obtained from 41 cohort studies from 16 countries.<sup>3</sup> This implies the inclusion of an additional 20 000 cases and 2.5 million deaths from study data from heavily polluted and densely populated countries such as China, whereas the WHO-GBD-IER mainly covered data from less polluted west-

ern regions such as Europe, Canada and the U.S.

In addition, IER mortality has been reported to be based on five major causes including coronary heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, lung cancer and lower respiratory tract disorders, while in the study by Burnett et al.<sup>3</sup> the development and application of GEMM was based on



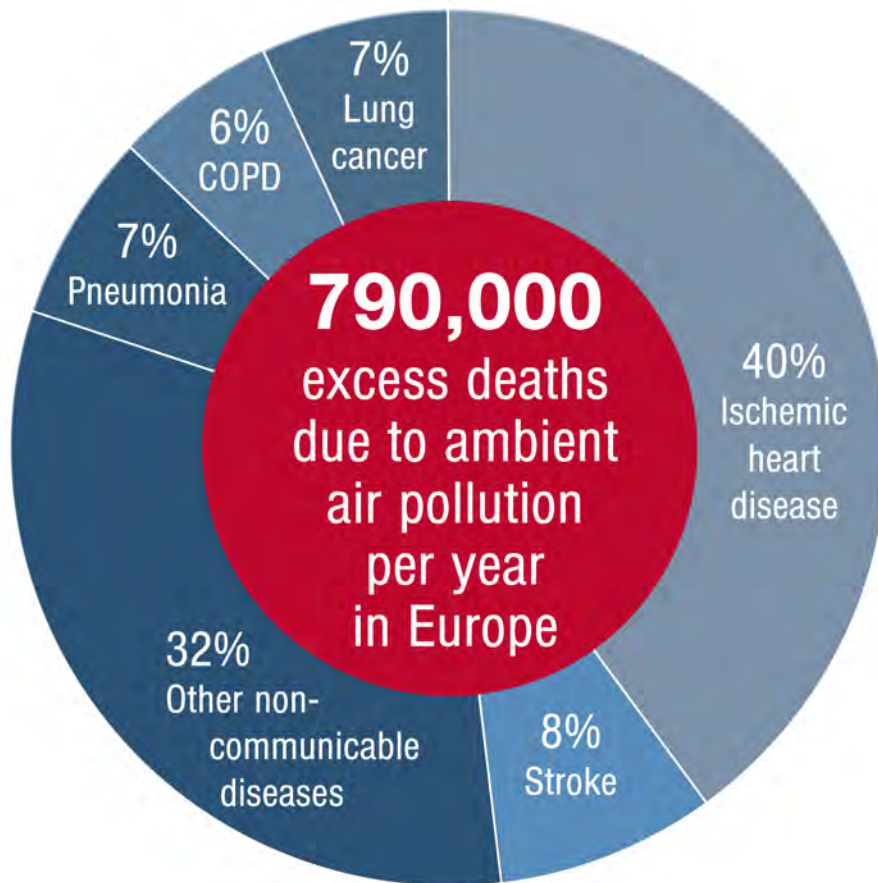


Figure 2. Estimated excess mortality attributed to air pollution in Europe and the contributing disease categories. At least 48% are due to cardiovascular disease (ischaemic heart disease and stroke). A fraction of other non-communicable diseases should also be counted to cardiovascular diseases related mortality, with an upper limit of 32%. COPD, chronic obstructive pulmonary disease

Image: © 2019, Oxford University Press

worldwide mortality data from all non-communicable diseases as well as pneumonia. The estimated additional air pollution death rate was 8.9 million, more than twice that of the GBD and WHO (4.2 million).

Recently, Lelieveld et al.<sup>4</sup> calculated that, based on the GEMM for Europe, this would result in up to 790,000 premature deaths per year mostly due to PM<sub>2.5</sub> exposure, more than twice based on the previous GBD-IER estimate (269,000) (Figures 1 and 2). Interestingly, the highest numbers of premature deaths occurred in Germany (154 per 100,000 per year), followed by Poland (150), Italy (136), France (105)

and the United Kingdom (98)<sup>4</sup> (Table 1). The main part of the mortality was due to cardiovascular diseases. As estimated by Jos Lelieveld et al., PM<sub>2.5</sub> air pollution reduces the European average life expectancy by 2.2 years.<sup>4</sup> To put this into perspective, the WHO estimates that the excess death rate from tobacco smoking is 7.2 million per year; hence, air pollution globally is now rated as the larger risk factor.

### Effects of air pollution on the cardiovascular system

When discussing the pathophysiological effects of air pollution, we focus on PM<sub>2.5</sub> because, in particular, the small particulate matter particles

can penetrate deeply into the lungs. Following inhalation of PM<sub>2.5</sub>, the fine aerosol particles are released into the bloodstream via a transition process and then absorbed into the blood vessel.<sup>5-7</sup> The particulate matter in the vessel wall stimulates the formation of reactive oxygen species, i.e., pro-oxidative substances and pro-inflammatory biological mediators (i.e., such cytokines as interleukin-6 and tumor necrosis factor) and acute phase proteins such as the C-reactive protein and the vasoconstrictor hormone endothelin.<sup>5-7</sup> These processes initiate or accelerate atherosclerotic changes. In general, the smaller the particle is (down to ultrafine particles <0.1 μm, PM<sub>0.1</sub>), the higher the probability of a rapid translocation of the particles into the vessel wall.<sup>7</sup>

Furthermore, activation of blood coagulation is observed. Accordingly, high levels of PM<sub>2.5</sub> are accompanied by hypercoagulation biomarkers, such as high plasma levels of fibrinogen and D-dimer and increased thrombin formation.<sup>5-7</sup> Human data show an inverse relationship between PM exposure and heart rate variability.<sup>5-7</sup> PM<sub>2.5</sub> can induce arterial hypertension via direct sympathetic activating effects in the brain<sup>6,7</sup> or by triggering endothelial dysfunction due to decreased vascular nitric oxide (NO) bioavailability.<sup>7</sup>

### The particulate matter limits for Europe are too high

In view of the WHO recommended guideline of 10 μg m<sup>-3</sup> for PM<sub>2.5</sub>, it can be assumed that more than 91% are exposed to higher concentrations worldwide. The European Union (EU) has been applying a mean air quality limit of 25 μg/m<sup>3</sup> for PM<sub>2.5</sub> since 2015, which is 2.5 times higher than the WHO guideline of 10 μg/m<sup>3</sup>. The

**Table 1. Estimated annual excess mortality attributed to air pollution\***

	All risks  Total CVD mortality (x10 <sup>3</sup> )	From air pollution#							
		CEV (x10 <sup>3</sup> )	IHD (x10 <sup>3</sup> )	CVD† (x10 <sup>3</sup> )	other NCD† (x10 <sup>3</sup> )	All diseases‡ (x10 <sup>3</sup> )	Deaths per 100,000	YLL (x10 <sup>6</sup> )	LLE (years)
Europe	2,138	64	313	377 (48%)	255 (32%)	790	133	14	2.2
EU-28	1,849	48	216	264 (40%)	249 (38%)	659	129	11.5	2.1
Germany	330	7	42	49 (40%)	48 (39%)	124	154	2.1	2.4
Italy	221	6	23	29 (36%)	35 (43%)	81	136	1.2	1.9
Poland	180	6	27	33 (57%)	13 (22%)	58	150	1.1	2.8
United Kingdom	147	3	14	17 (27%)	29 (45%)	64	98	1.1	1.5
France	144	3	13	16 (24%)	38 (57%)	67	105	1.1	1.6

\* Data for all EU countries, including 95%CI, are given in the supplement (overall uncertainty about ±50%).

# CEV is cerebrovascular disease, IHD is ischaemic heart disease, CVD are total cardiovascular diseases (CEV+IHD), NCD are non-communicable diseases. YLL are years of life lost. LLE is loss of life expectancy.

† Percentages refer to fractional contributions of CVD and other NCD to attributable mortality from all diseases.

‡ All diseases refer to NCD+LRI

target is 20µg/m<sup>3</sup> by 2020, which is considered too high as well due to the new data. For comparison, the annual average limit in the US is 12 µg/m<sup>3</sup> (since 2012) and in Canada 10 µg/m<sup>3</sup> (since 2015), which are to be further reduced in the future. In Australia, the annual PM<sub>2.5</sub> limit is 8 µg/m<sup>3</sup>, which should be further reduced to 7 µg/m<sup>3</sup> by 2025.

## Key points:

- Due to air pollution (PM<sub>2.5</sub> and ozone), there are 8.9 million deaths per year worldwide.
- Almost 800,000 premature deaths per year are calculated in Europe, with coronary heart disease and stroke predominating, especially with around 50% of premature deaths.
- The number of deaths from particulate matter worldwide exceeds the number of deaths caused by smoking.
- The limit for Europe must, therefore, be drastically reduced

- Air pollution must be recognised as a cardiovascular risk factor and be mentioned in the guidelines of the European Society of Cardiology for Prevention, Heart Attack and Stroke and evaluated accordingly.

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## Professor Thomas Münzel

University Medical Center of the Johannes Gutenberg-University Mainz  
Department of Cardiology  
Tel: +49 613 117 7250  
[tmuenzel@uni-mainz.de](mailto:tmuenzel@uni-mainz.de)

## Professor Jos Lelieveld

Max Planck Institute for Chemistry,  
Johannes Gutenberg University Mainz  
[jos.lelieveld@mpic.de](mailto:jos.lelieveld@mpic.de)



# Supporting the addition of asthma medications to the exemption list in the UK

Dr Fred A. Wagshul, Pulmonologist and Medical Director at the Lung Center of America, explains why he supports the addition of asthma medications to the exemption list in the UK

I read with great interest the article on the Open Access Government website from Asthma UK about [How Unfair Prescription Charges are Putting People with Asthma at Risk](#). It is true that in the UK, the U.S. and elsewhere throughout the world, the cost of treating chronic asthma is astronomical and can be virtually unsustainable for many with limited financial resources who struggle to breathe every day. So let me say at the outset that I support the addition of asthma medications to the exemption list in the UK.

But as I read the following in the Open Access Government post, "People with asthma have to take their medication every day...They need...a 'preventer' inhaler...and a 'reliever' inhaler...and many...need allergy medication...or antibiotics", I felt compelled to offer some information that will be surprising to most, and it is this: These patients don't have to live that way.

There is sound, medically scientific proof that the symptoms of asthma can be eradicated. The treatment protocols that can accomplish this should be adopted not only to bring down the costs associated with the treatment of asthma but more importantly, to bring these people who struggle to breathe daily the ability to breathe easily for life.

For many people dealing with the scourge of chronic asthma, the notion of living symptom-free of asthma for life borders on the absurd. That's because the 'band-aid' drugs commonly prescribed for asthma – inhalers, relievers, allergy meds and more – cause patients to become dependent upon those drugs for life. But medical studies published in some of the world's most highly respected medical journals clearly show that by identifying the root cause of a patient's asthma and treating that, the symptoms can be



altogether obliterated. This would obviate the need for long-term medications, rescue inhalers (many of which contain dire black box warnings), emergency room visits and hospitalisations.

Studies have demonstrated that certain bacteria (i.e. *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*) are associated with pulmonary disorders, including asthma. Therefore, the specific bacteria identified in a patient's system can be targeted through the development of an individually prescribed antibiotic protocol that has proven to be tremendously successful.

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**“There is sound, medically scientific proof that the symptoms of asthma can be eradicated. The treatment protocols that can accomplish this should be adopted not only to bring down the costs associated with the treatment of asthma but more importantly, to bring these people who struggle to breathe daily the ability to breathe easily for life.”**

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What this means is that people with asthma, COPD, chronic bronchitis and even emphysema do not have to live with life-limiting breathing difficulties. They can live symptom-free and even find total remission from their debilitating symptoms. Many of our patients, who had experienced significant declines in the quality of their lives have returned to their normal, active lives. Many of our patients' experiences can be found here: <https://www.lungcenterofamerica.org/stories>

It is heartbreaking to learn from the Open Access Government post that, “The number of adults with a lifetime diagnosis of asthma in the UK is increasing and the UK death rate from asthma is among the worst in Europe.” These statistics are unacceptable – since we know what works to prevent the suffering of this magnitude. I have been asked by so many of my patients why, if I can put their asthma into remission, other doctors aren't doing the same thing. Here's why.

Firstly, I know for certain that the use of long-term antibiotics is essential in treating the cause of asthma, rather than just the symptoms. This protocol is not popularly accepted by mainstream medicine, despite documented excellent outcome data as published repeatedly in prestigious medical journals. (See study links at <https://www.lungcenterofamerica.org/>).

Secondly, \$80 billion is spent annually in the U.S. just



*Dr Fred A. Wagshul  
Pulmonologist*

on the treatment of asthma alone. Approximately 70% of the costs of asthma care are generated through emergency room visits and subsequent hospitalisations. Over 98% of all physicians/physician groups nationwide are tied to hospital reimbursement systems that help subsidise physician salaries. If that 70% was left unspent, most of these physician groups would collapse. Additionally, the out-of-pocket costs incurred by patients in the U.S. is on average, \$3,000. This is in addition to the premiums they pay for health insurance. It's a financial house of cards.

All of this is in stark contrast to our office patients who are treated for the root cause of their breathing difficulties, (over 20,000 and climbing). They rarely go to the emergency room or are ever hospitalised, so that is why Lung Center of America has one of the lowest hospitalisation rates for pulmonary patients in the nation.

It is my fervent hope that this information will be shared with those empowered to review and approve asthma medications for the exemption list in the UK. Even more importantly, it is imperative that patients who struggle to breathe understand that they most certainly do not have to live that way. ■

**Dr Fred A. Wagshul  
Pulmonologist**

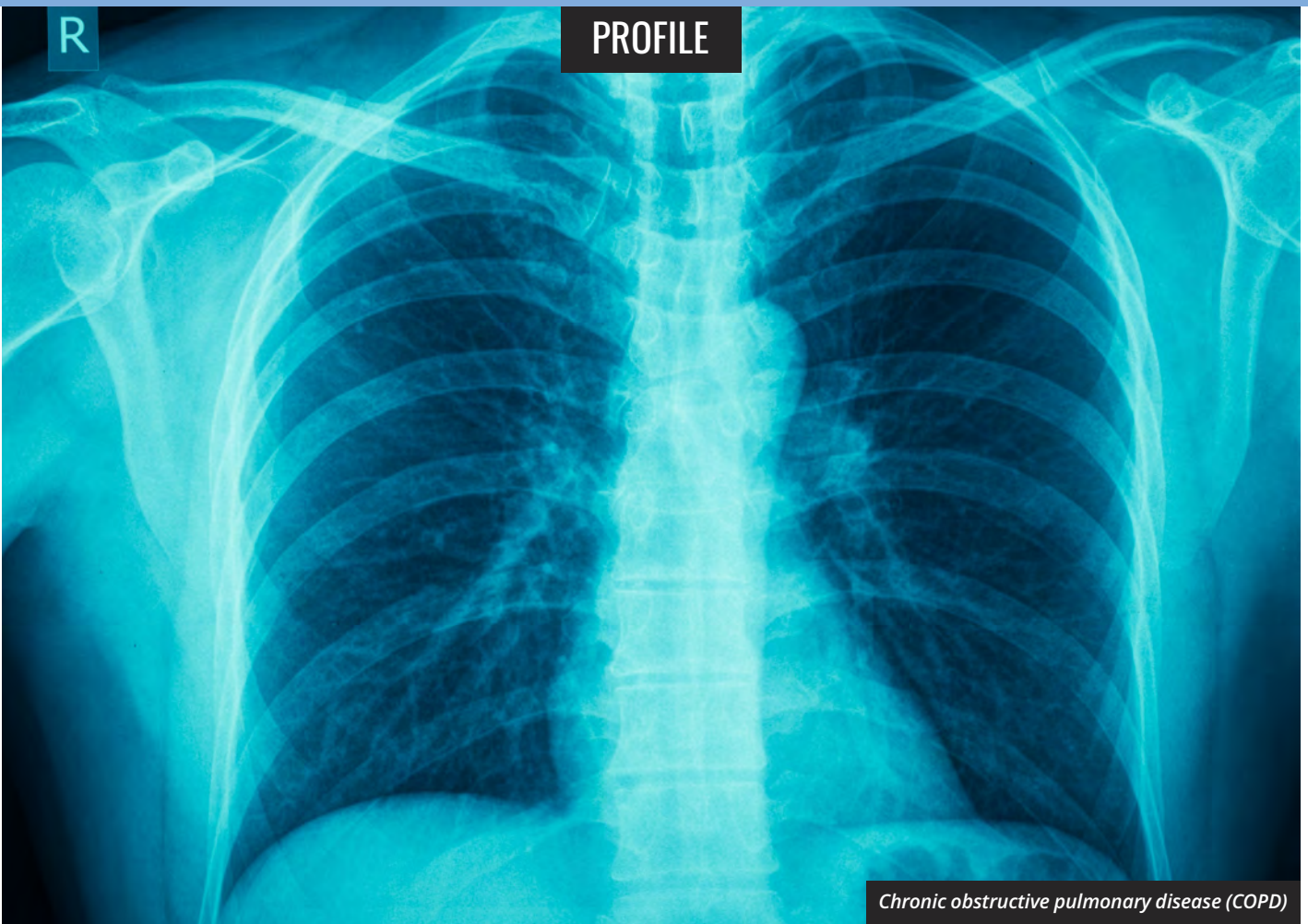
**Medical Director**

Lung Center of America

Tel: +1 (937) 859 5864

[info@lungcenterofamerica.com](mailto:info@lungcenterofamerica.com)

[www.lungcenterofamerica.org](http://www.lungcenterofamerica.org)

*Chronic obstructive pulmonary disease (COPD)*

# Fine dust air pollution (PM<sub>2.5</sub>) as a cause of chronic inflammatory lung diseases?

Michael Roth, Research Group Leader at University Hospital Basel asks if fine dust air pollution (PM<sub>2.5</sub>) is a cause of chronic inflammatory lung diseases and provides a most engaging response

**C**hronic airway inflammatory diseases including asthma, chronic obstructive pulmonary disease (COPD) and lung fibrosis have been increasing worldwide for several decades. The initiation of asthma is often seen as an allergic over-reaction, however, over 45% of the patients are not linked to an allergic response. The cause of lung fibrotic diseases is largely unknown, but recent studies indicate that fine dust might be involved in the pathogenesis.

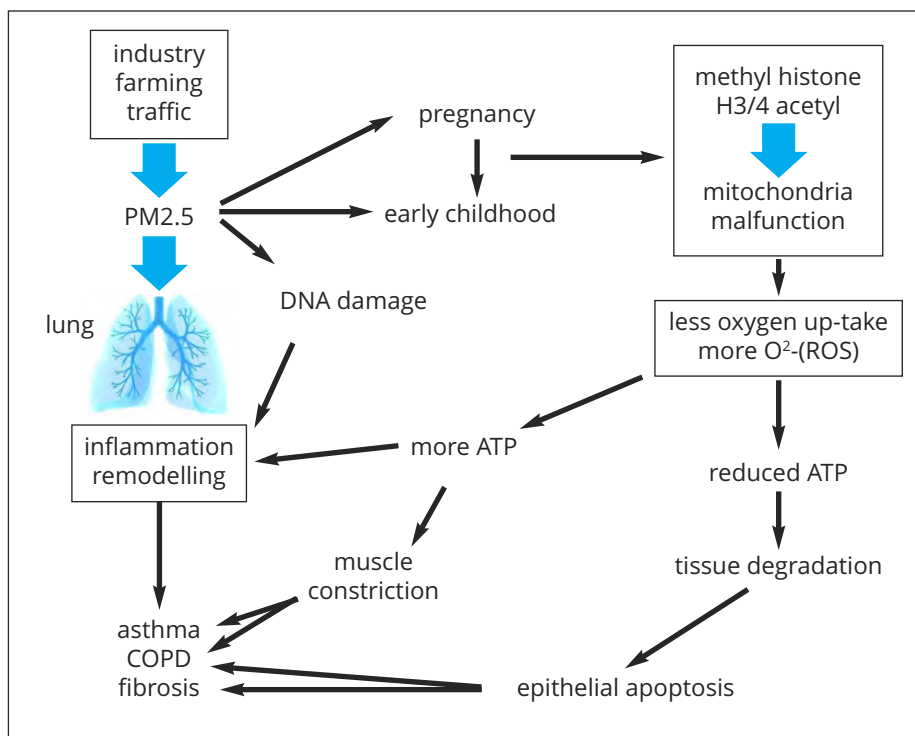
Regarding COPD, the cause seems to be clear: cigarette smoking, while the

mechanism by which inhaled cigarette smoke starts the pathogenesis of COPD is not well understood. Fine dust air pollution with particulate matter < 2.5 micron (PM<sub>2.5</sub>) has been recognised to contribute to the progression of all three chronic inflammatory lung diseases. Thus, one could question is if it should be considered as a major cause.

PM<sub>2.5</sub> air pollution is a serious global health problem, especially in the extending urban areas of the ever-growing major cities. PM<sub>2.5</sub> air pollution originates from open cooking fires

(gas, petrol, wood), traffic, industry and agriculture. Moreover, PM<sub>2.5</sub> is also a major component of cigarette smoke and it can easily pass through the cigarette filters.

Several studies showed that exposure to PM<sub>2.5</sub> increased the prevalence of chronic inflammatory diseases of the immune system, the lung, the cardiovascular and gastrointestinal organs. A new threat is presented by fine plastic particles that can enter the human food chain through fish and seafood. It was thought that the major problem with such particles was their toxicity,



*Figure 1: Inhaled PM2.5 can pre-dispose the lung during late embryogenesis and early childhood to develop chronic inflammatory lung diseases later in life. The mechanisms which lead to epigenetic modified gen activity and malfunction of tissue forming cells is largely unknown*

which varies with their chemical composition. However, new studies indicated that the real problem is their tiny size. For most organisms, it is difficult to get rid – excrete – such small particles once they are in the body, regardless if they were inhaled, ingested or taken up by other ways.

Regarding the lung, it has been reported that repeated exposure to PM2.5 accelerated the decline of lung function, caused irreversible airway wall remodelling and increased the exacerbation rate in asthma patients. Even in the healthy lung, PM2.5 increased oxidative stress and the expression of pro-inflammatory cytokines and growth factors, which had been associated with asthma, COPD and fibrosis.

What is more worrying, are the observations that exposure to PM2.5 during embryogenesis and during early childhood (years 0-6) predisposes the lungs to develop chronic inflammatory lung diseases later in life. The molecular biological mechanism(s) by which PM2.5 leads to chronic lung inflammation remains largely unknown (Fig. 1). Toxicity due to the chemical nature of PM2.5 is one aspect of their action, but this applies mainly to soluble particles.

The size of insoluble PM2.5 compounds is the biggest concern. These small particles can be taken up not only by specialised immune defence cells, such as macrophages but also by tissue forming cells (muscle cells, connective tissue cells, etc.). Once inside a cell, the small particles activate an inflamma-

tion-like response, which aims to get rid of them, but which is most often not successful (Fig. 1).

Inhaled PM2.5 is deposited in the mucosa, causing epithelial cell damage, a typical pathology of asthma and COPD. PM2.5 stimulated the release of inflammatory mediators and lowered the threshold of allergic responsiveness, thus, they may increase the frequency of exacerbation in asthma and COPD. Moreover, some reports indicated that the effect of inhaled PM2.5 are different when they are deposited in the larger airways, compared to in the smaller airways, or in the alveoli where the gas exchange ( $O_2$  exchange for  $CO_2$ ) takes place. Thus, understanding the cell and molecular biological effects of insoluble PM2.5 particles seems to be crucial if we want to find therapies or cures for the diseases they cause.

Increasing evidence shows that PM2.5 can induce epigenetic modifications that regulate the gene activity on multiple levels, such as histone and DNA structure. Earlier, I reported that epigenetic events may underlie the “inheritable” predisposition of the lung to chronic inflammatory diseases. In this regard, mitochondria have to be considered to play a central role. The mitochondria are so-called organelles and are partly independent of the cells function and they have their own DNA and specific proteins. Mitochondria are the cell’s power stations and their function is essential for life. Modified mitochondria activity was linked to metabolic diseases, inflammation, cancer and tissue degeneration. PM2.5 can modify the function of mitochondria.

PM2.5 affected the function of mito-



chondria and the endoplasmic reticulum. In animal models, PM2.5 induced (i) endoplasmic reticulum stress, (ii) disturbed embryonal development and (iii) initiated the formation of fibrotic lesions in other organs other than the lung. In more details, Akt – mTOR signaling regulated mitochondria activity through mitochondria-associated endoplasmic reticulum membranes.

This observation linked PM2.5 to our own studies on Akt – mTOR signaling as a central regulator of mitochondria function which controls tissue remodelling in chronic lung inflammation. In allergic asthma, we showed that IGE over-activated the inflammatory Akt – mTOR signaling by down-regulating its inhibitor PTEN, which controls also the interaction between mitochondria and the endoplasmic reticulum. This suggests that the interaction between mitochondria and the endoplasmic reticulum is part of the pathogenesis of asthma and may also be relevant to other chronic inflammatory lung diseases.

The endoplasmic reticulum is closely linked to mitochondria function and together, they regulate protein synthesis, protein folding and cellular calcium metabolism. The balance between these mechanisms is crucial to prevent chronic lung inflammation. The control of hormone receptors and histones is central to the effect of drugs used in the therapy of chronic inflammatory diseases.

What is known about the effects of PM2.5 on mitochondria? In rats, inhaled PM2.5 increased the formation of radical oxygen species (ROS) which caused the dysfunction of mitochondria. In other studies, PM2.5 reduced

the oxygen consumption of mitochondrial oxygen, thereby, it decreased ATP production and caused mitochondria fragmentation. The result of this reduced energy production by mitochondria was cell death, which may be linked to the decay of the lung tissue which often occurs during the end-stage of COPD and is called emphysema. Regarding COPD, PM2.5 contained in cigarette smoke modified the methylation pattern of DNA and proteins also in non-smokers.

Concerning asthma, increased death of epithelial cells by PM2.5 exposure might explain the disrupted structure of the epithelium that lines the bronchus and is the barrier for inhaled dust, bacteria and viruses. PM2.5 caused histone hyper-methylation, thereby, modifying the accessibility of genes for transcription proteins. What is particularly worrying is the observation that such a process could happen during embryogenesis and the effects were lasting into childhood.

In animal models, exposure to PM2.5 early in life induced epigenetic predisposition to asthma-like symptoms such as, increased oxidative stress and extracellular matrix remodelling; which were handed down to the next generations. Particles that are < PM2.5, – PM0.1 –, have even been found accumulated inside mitochondria and caused severe damage to the mitochondrial DNA. Unfortunately, only a small number of studies have ever attempted to investigate this effect of small particles.

Mitochondria activity was up-regulated in asthmatic mesenchymal cells through the protein methylation catalysing protein PRMT1. However, in COPD, the same mechanisms caused

the deterioration of mitochondria. In other animal models, PRMT1 was the major regulatory enzyme for mitochondrial proteins. It has not been investigated if the same mechanism is relevant to the pathogenesis of chronic inflammatory lung diseases in humans.

## Conclusion

We need to find new therapies. For asthma alone, the number of patients doubles every decade and affects 350,000,000 people worldwide at present. The facts that (i) Exposure to PM2.5 during late embryogenesis and repeated exposure during early childhood predisposes the lungs to develop chronic inflammation later in life; (ii) PM2.5 induces epigenetic modifications of proteins and DNA and; (iii) These epigenetics can be handed down over generations – strongly suggest that we need to understand this mechanism(s) when we want to find new therapies and cures for chronic inflammatory lung diseases.



**Michael Roth**  
**Research Group Leader**  
 University Hospital Basel  
 Tel: +41 61 265 2337  
[Michael.roth@usb.ch](mailto:Michael.roth@usb.ch)  
<https://biomedizin.unibas.ch/en/research/research-groups/roth-tamm-lab/>

# A devastating cancer: The priorities for brain tumour research

Chief Executive of Brain Tumour Research, Sue Farrington Smith MBE, outlines the priorities for research into brain tumours and why it is imperative we overcome this uniquely devastating cancer

Combating brain tumours must be a priority for policymakers. Not only does this devastating disease kill more children and adults under the age of 40 than any other cancer, but, according to a recent report by the Westminster All-Party Parliamentary Group on Brain Tumours, for which we provide the Secretariat, it also has the third highest societal cost, after lung and breast cancer.

This situation is a result of underinvestment into research into brain tumours, which, historically, received just 1% of the national spend on cancer research.

This lack of funding has meant that, unlike many other forms of generally more common and well-known cancers, the scientific knowledge underpinning an interpretation of why and how this cancer develops is still in its infancy. This has led to a paucity of treatment options. No brain tumour treatments have been developed and approved for use on brain tumours since 1999 when chemotherapy drug Temozolomide received the first authorisation, yet 64 have been approved for blood cancers and 15 for breast cancer. Sadly, according to the latest statistics, less than 20% of those diagnosed with a brain tumour will survive beyond five years of their diagnosis.<sup>1</sup>

## **Sustainable and collaborative research must be a priority**

For progress to occur in medical research, researchers must be motivated by the prospect of continuous research funding, leadership opportunities and ground-breaking scientific advances. A lack of such incentives will only hamper growth and success.

Research capacity can only be bolstered, sustained and grown by ensuring researchers can operate within a framework that encourages the generation of new

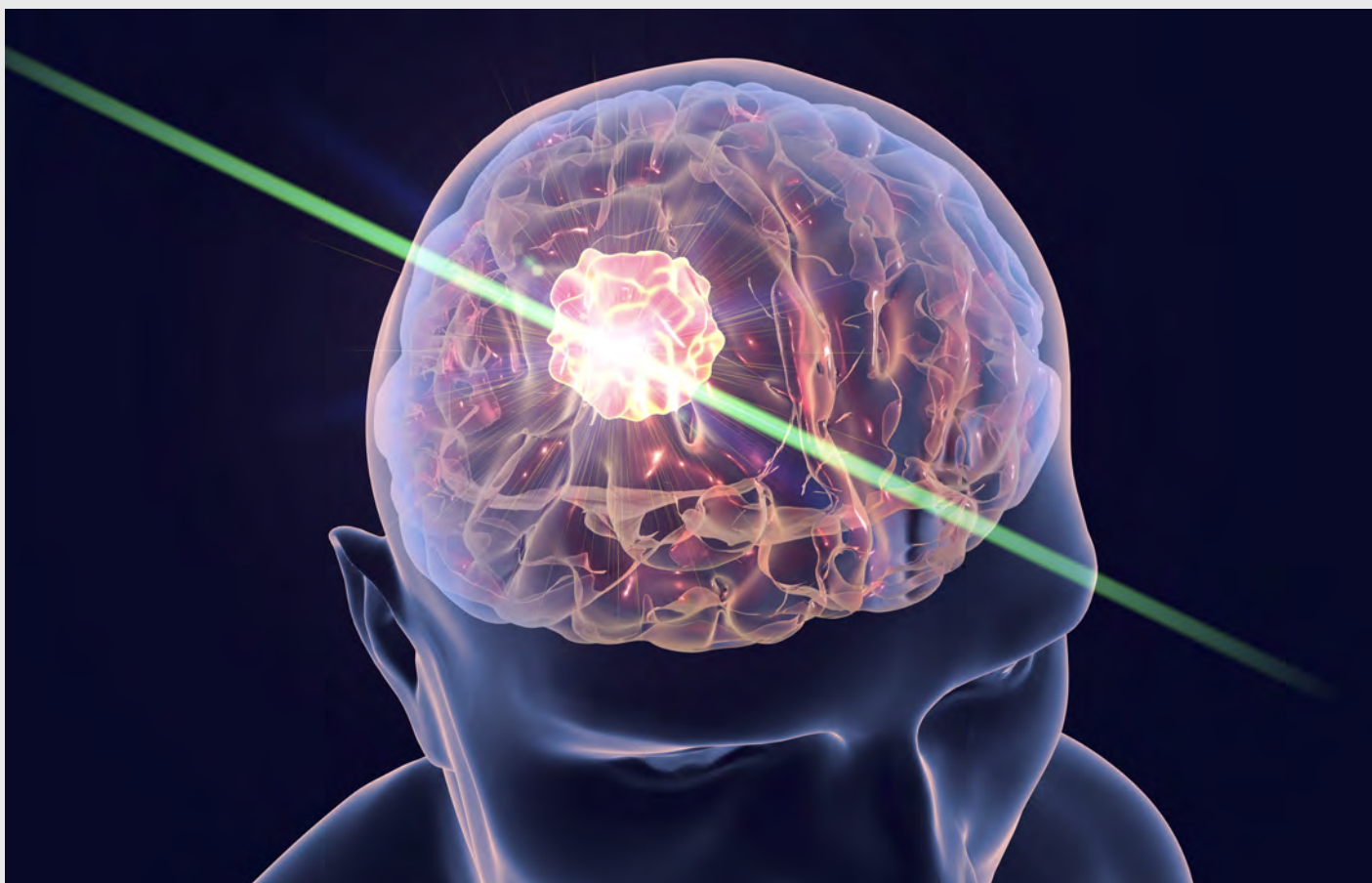
ideas and the discovery of breakthroughs from which they can translate their findings from the laboratory bench to the patient's bedside. This can be effectively facilitated within the environment a research centre creates. Brain Tumour Research has already established four dedicated centres in pioneering research, which is enabling us to attract other funding for these centres as a result.

## **How government can improve outcomes for brain tumour patients**

Working tirelessly to hold the government and larger charities to account, Brain Tumour Research led the campaign behind a 2015 e-petition, calling for the government to fund more research into brain tumours. Galvanising more than 120,000 signatures, the petition led to an Inquiry by the House of Commons' Petitions Committee, a Westminster Hall debate and the formation of a Department of Health and Social Care (DHSC) Task and Finish Working Group on Brain Tumour Research.

The publication of the Task and Finish Group's report in February 2018 heralded a significant shift in focus and led to a £20 million UK Government funding announcement and a pledge of £25 million from Cancer Research UK (CRUK). The tragic death of Dame Tessa Jowell from a brain tumour, following her moving personal testimonies and calls for change, proved a catalyst for the establishment of the Dame Tessa Jowell Brain Cancer Mission (TJBCM). A further £20 million government funding pledge followed, bringing the total pledge to £65 million (including CRUK's funding) over the next five years (£13 million per year) to facilitate a cure for brain tumours.

This is all moving in the right direction but there is still so much more to be done. In our newly published Find



A Cure manifesto, we outline a series of measures, centred around growing capacity, building research infrastructure and accelerating treatments, which are needed to further progress research into brain tumours, including:

- NHS Trusts should ensure clinicians have ring-fenced, protected time to carry out clinical research into new and better treatments.
- The creation of a national register of all site-specific cancer research to track all research work, grants and results to avoid duplication and enable collaboration.
- Working with brain tumour charities to extend the BRAIN UK tissue bank across the nation, investing in the infrastructure and regulation required for brain tumour tissue samples.
- Calling on the government's National Institute for Health Research to encourage and facilitate the successful applications for research into brain tumours needed to find a cure.

Implementing these policies, combined with sustained research funding, would facilitate innovation and

accelerate access to treatments for patients. This is vital if we are to achieve parity with other cancers such as breast and leukaemia and give hope to the thousands of people diagnosed with a brain tumour every year in the UK.

Visit <https://www.braintumourresearch.org/campaigning/why-we-campaign> to read Find A Cure in full. ■

1 Cancer survival in England – adults diagnosed 2012 – 2016. Available at <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/datasets/cancersurvivalratescancersurvivalinenglandadultsdiagnosed>

**Sue Farrington Smith MBE**  
**Chief Executive**

Brain Tumour Research

Tel: +44 (0)1908 867 200

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# Intramembrane proteases in neurodegenerative diseases

Prof Dr Regina Fluhrer, from the University of Augsburg, explains how intramembrane proteases have been implicated in the emergence of neurodegenerative diseases

**N**eurodegeneration is characterised by a progressive loss of neurons being the hallmark of a variety of neurodegenerative diseases, including Amyotrophic Lateral Sclerosis, Parkinson's disease, Alzheimer's disease and Huntington's disease.

Despite extensive research efforts, the molecular mechanisms of neurodegeneration are still not comprehensively understood, and the corresponding diseases are incurable.

**“From the discovery of the first soluble proteases it took almost 150 years before the first protease-targeting drug entered the market. But today protease-targeting drugs are indispensable in treatment of several diseases, among them HIV, cancer and hypertension.”**

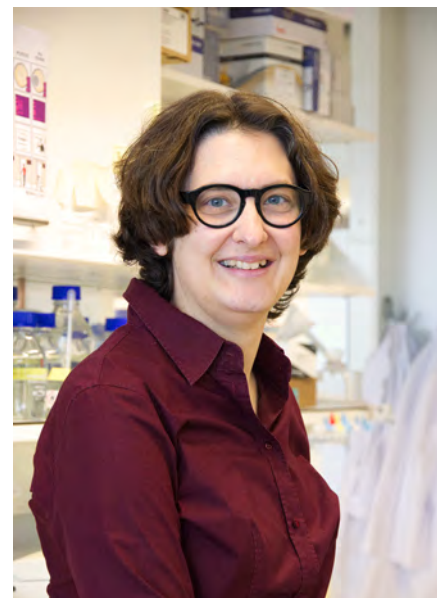
In recent years intramembrane proteases have been implicated in emergence of different neurodegenerative diseases. This intriguing protease family cleaves its substrates in the plane of cellular membranes (read more in the [October 2018](#) edition of Open Access Government), either degrading their substrates or releasing protein fragments capable of transferring signals across membranes (read more in the [January 2019](#) edition of Open Access Government).

The best studied intramembrane protease, in the context of neurodegener-

ation, is presenilin, an aspartyl intramembrane protease that contributes to the development of amyloid plaques, one pathological hallmark of Alzheimer's disease. In contrast to all other intramembrane proteases, presenilin requires the formation of a protein complex to be active.

Its partners in this complex, which is termed  $\gamma$ -secretase, are the proteins nicastrin, Aph-1 and Pen-2. Only if all four partners assemble correctly, presenilin is active and cleaves its substrates, among them the  $\beta$ -Amyloid-Precursor Protein (APP), which harbours the  $\beta$ -Amyloid peptide found to aggregate in brains of Alzheimer's disease patients. Before APP is accessible to  $\gamma$ -secretase it needs to be cleaved by an independent protease in its extracellular domain, which is thereupon secreted.

In principle, two proteases can mediate this initial cleavage. If  $\alpha$ -secretase, represented by ADAM10, cleaves APP, the  $\beta$ -Amyloid peptide is destroyed, and  $\gamma$ -secretase liberates a peptide that is not aggregating (non-amyloidogenic processing). If  $\beta$ -secretase, represented by BACE-1, cleaves APP, the subsequent cleavage by  $\gamma$ -secretase liberates the  $\beta$ -Amyloid peptide (amyloidogenic processing) (Figure 1). The cleavage of APP by  $\gamma$ -secretase, is not precise, but liberates  $\beta$ -Amyloid peptides of different length. This results from multiple-cleavages of presenilin in the transmembrane domain of its



*Regina Fluhrer, professor of Biochemistry and Molecular Biology, Faculty of Medicine, University of Augsburg, Germany*

substrate. A phenomenon that is also observed for other intramembrane proteases and commonly referred to as processivity.

The longer the  $\beta$ -Amyloid peptides, the better they aggregate. Interestingly, patients that carry mutations in one of their presenilin genes produce more of the longer  $\beta$ -Amyloid peptides and suffer from early onset Alzheimer's Disease, also known as familial Alzheimer's disease (FAD), that is typically characterised by a more rapid and aggressive progress. Based on this, inhibition of presenilin to abolish  $\beta$ -Amyloid peptide production or modulation of its processivity to favour production of shorter  $\beta$ -Amyloid peptides became an attractive treatment strategy.

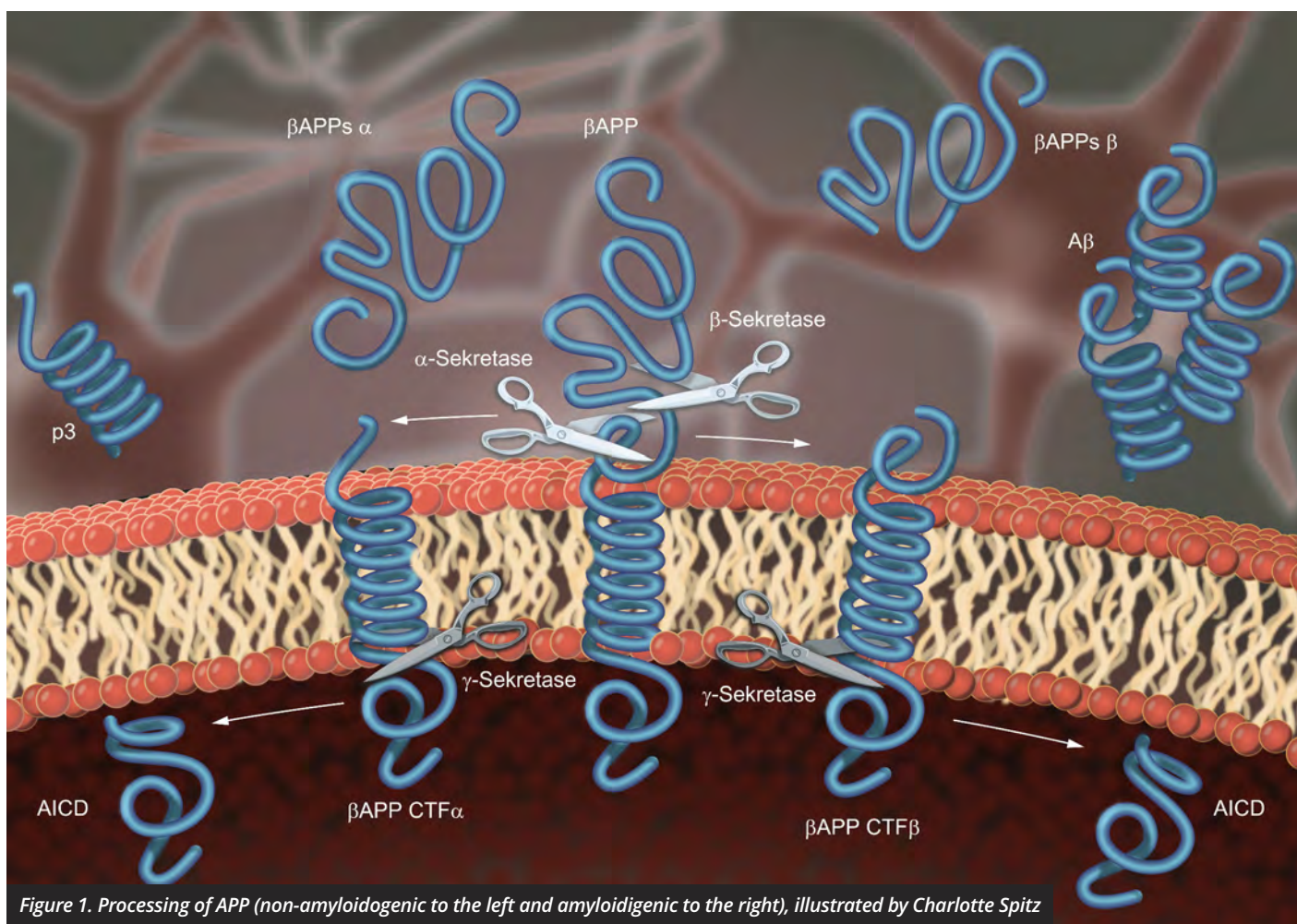


Figure 1. Processing of APP (non-amyloidogenic to the left and amyloidogenic to the right), illustrated by Charlotte Spitz

However, so far, all candidate drugs tested in clinical studies failed to improve the disease. Although this is disappointing, it is unjustified to dump presenilin as a drug target at this stage. All clinical trials relied on patients that already suffered from at least mild cognitive impairment, but changes in neuronal metabolism occur long before clinical symptoms can be observed. This implies that  $\beta$ -Amyloid reducing therapies must be applied even before patients are diagnosed with dementia and in turn requires the identification of valid biomarkers that allow a reliable diagnosis of Alzheimer's disease at a very early stage.

From basic research we also know that, similar to other intramembrane

proteases, presenilin cleaves an extensive spectrum of substrates, among them the NOTCH receptor (read more in the [January 2019](#) edition of Open Access Government), explaining why  $\gamma$ -secretase inhibition failed due to serious side effects.

**"It is undisputed that intramembrane proteases contribute to important cellular pathways, which upon malfunction cause severe diseases, like neurodegeneration."**

Moreover, another family of aspartyl intramembrane proteases, the SPP/SPPL proteases, shares its active site architecture with  $\gamma$ -secretase, and it is known that drugs targeting  $\gamma$ -secretase can also affect this protease family. However, physiological function

and substrate spectra of SPP/SPPL proteases have just recently begun to emerge (read more in the [January 2019](#) and [April 2019](#) editions of Open Access Government).

Another intramembrane proteases that has been recently implicated in neurodegeneration is PARL, an intramembrane serine protease that localises to mitochondria. An altered turnover of damaged mitochondria is part of the reason why dopaminergic neurons die and cause Parkinson's disease. PARL cleaves a mitochondrial protein, termed PINK, that is implicated in this mitochondrial turnover and, thus, PARL is suggested as a possible target for treatment of Parkinson's disease. Currently this assumption, cannot be tested since inhibitors, which selectively

target PARL are not available. The development of selective inhibitors against intramembrane proteases is challenging, since their cleavage mechanisms and the influence of the microenvironment present in the membranes are poorly understood. Also, the structures of intramembrane proteases, which may facilitate the development of inhibitors, are difficult to solve and to date the structure of only one human intramembrane protease and a limited number of non-human homologues has been solved.

**“The best studied intramembrane protease, in the context of neurodegeneration, is presenilin, an aspartyl intramembrane protease that contributes to the development of amyloid plaques, one pathological hallmark of Alzheimer’s disease.”**

Furthermore, the biological function of PARL in mitochondria has not been unravelled and its whole substrate spectrum has just begun to emerge, which averts the prediction of potential side effects that may be caused by PARL inhibition.

Accumulating evidence indicates the neuroinflammation, which involves microglia, contributes to the pathogenesis of multiple neurodegenerative diseases. In the peripheral immune system, which includes all players of the immune system outside the brain, intramembrane proteases take on important tasks (read more in the

April 2019 edition of Open Access Government). Future studies will bring to light whether this holds also true for microglia, the representatives of the immune system in brain.

From the discovery of the first soluble proteases it took almost 150 years before the first protease-targeting drug entered the market. But today protease-targeting drugs are indispensable in treatment of several diseases, among them HIV, cancer and hypertension. Since intramembrane proteases were discovered only about 20 years ago, it is not surprising, that at present no drugs targeting these enzymes are available.

Nonetheless, it is undisputed that intramembrane proteases contribute to important cellular pathways, which upon malfunction cause severe diseases, like neurodegeneration. If sustained and unbiased research approaches continue to better understand these enzymes and their physiological function, I am convinced that they will become valuable drug targets, not only for treatment of neurodegenerative diseases but also other, so far not curable diseases, way before another 150 years have passed.

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**Prof Dr Regina Flührer**  
 Biochemistry and Molecular Biology,  
 Faculty of Medicine,  
 University of Augsburg,  
 Germany  
 Tel: +49 821 598 - 2069  
[regina.fluhrer@med.uni-augsburg.de](mailto:regina.fluhrer@med.uni-augsburg.de)  
<https://www.uni-augsburg.de/>



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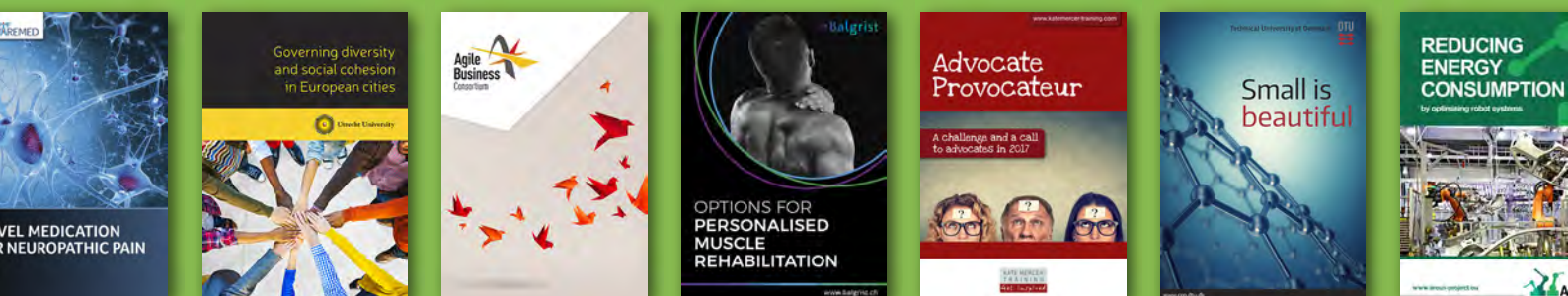
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# Impact and early intervention: Clinical research into osteoarthritis

Versus Arthritis speaks to award-winning rheumatologist Dr Fiona Watt about clinical research into osteoarthritis

**D**r Fiona Watt, based at Oxford's Kennedy Institute of Rheumatology, was recently awarded a prestigious [UK Research and Innovation Future Leaders Fellowship](#). The fellowship will also allow Dr Watt and her team to explore the development of new treatments to manage the pain caused by [osteoarthritis](#).

The condition, once thought to be limited to the elderly, affects 9 million people of all ages in the UK. The focus of this research (which is about early intervention) could be life changing for people living with chronic pain.

Osteoarthritis can affect any joint in the body. Discomfort can be experienced in the hips, hands and knees and can impact mobility. Osteoarthritis is associated with roughening of cartilage and damage to the joint which can lead to significant pain and stiffness. Depending on individual circumstances, there may be limited options for treatment.

Dr Watt explains: "We know current perceptions and misconceptions about arthritis are causing two in five people with the condition to feel isolated on a regular basis. This can mean people don't seek the treatment or support they need to live well or identify positive preventative strategies early on in the condition."

Recommended treatments for osteoarthritis begin with steps that people can take without being reliant on medication, such as regular physical activity, especially in the form of walking, strengthening exercises for particular joints and maintaining a healthy weight. Everyone's experience of arthritis is different, so we recommend people to discuss their self-management options with a healthcare professional.

For some, medications such as common topical treatments to manage pain such as over the counter

[Non-steroidal anti-inflammatory drug \(NSAID\)](#) gels or creams can be useful in pain relief. Topical treatments may be effective for managing pain in the knees and hands but may be less so in alleviating discomfort in the hips. For those needing stronger pain relief, they may be prescribed other tablet medication following a consultation with their GP.

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*"Patients we've talked to do have an awareness that osteoarthritis is a disease that isn't generally well-understood by both patients and some healthcare providers."*

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## Acute joint injury clinical studies

To try to improve understanding of osteoarthritis, Dr Watt has conducted studies with a focus on a subgroup of people who have experienced an acute joint injury, which is a major risk factor for future osteoarthritis.

She shares her findings: "In these studies, we see around 50% of individuals develop so-called 'post-traumatic osteoarthritis'. Using a combination of imaging to detect changes in the joint and patient-reported outcome measures, we have shown that joint injury triggers an immediate, inflammatory, mechanically driven response, some of which appears necessary for later osteoarthritis."

Dr Watt continues, "Being able to predict who will develop osteoarthritis, either as a result of injury or just by getting older, is something that we believe is essential for us to make progress in preventing and treating this disease."

## Healthcare practitioners are addressing the knowledge gap

More healthcare practitioners are increasing their knowledge about how arthritis can impact their



Dr Fiona Watt

would give practitioners insight that ultimately better supports patients in exploring their current treatment options and us as researchers were able to develop new treatments.”

### Frontline support through core skills workshops

The majority of people living with musculoskeletal conditions are managed in primary and community-based care. On average, 1 in 5 people in the UK consults their GP about a musculoskeletal condition every year. The rate of demand on the frontline has identified a training need which has been addressed by Versus Arthritis’ development of a [Core Skills programme](#) which aims to drive improvement in healthcare delivery.

Core Skill programme [workshops](#) are designed specifically for healthcare professionals and run throughout the year across the UK. They deliver improved skills in treating patients with musculoskeletal conditions including osteoarthritis.

Investing in the development and dissemination of new training and education resources for professionals will have a direct impact on improved patient care. These core skills support identifying appropriate treatments at the right time to make a positive impact in the lives of people with arthritis. ■

Dr Fiona Watt leads the Versus Arthritis Musculoskeletal Disorders Research Advisory Group and divides her time between two centres of excellence supported by the charity: the [Centre for Osteoarthritis Pathogenesis](#) and the [Centre for Sport, Exercise and Osteoarthritis](#).

The Core Skills programme has been developed in collaboration with the [Royal College of General Practitioners \(RCGP\)](#). For more information about e-learning and workshops for professionals, visit <https://www.versusarthritis.org/about-arthritis/healthcare-professionals/core-skills-in-musculoskeletal-care/>.

### Dr Fiona Watt University Research Lecturer

Oxford’s Kennedy Institute of Rheumatology on behalf of Versus Arthritis

Tel: +44 (0)1865 612 642

[fiona.watt@kennedy.ox.ac.uk](mailto:fiona.watt@kennedy.ox.ac.uk)

[www.kennedy.ox.ac.uk](http://www.kennedy.ox.ac.uk)

[www.versusarthritis.org](http://www.versusarthritis.org)

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patients’ lives. More people from a range of ages are visiting their local healthcare providers with questions about symptoms. Arthritis can be diagnosed as the root cause of pain, rather than being mistaken for common aches and pains. This is important to ensure individuals can receive the appropriate treatment at the right time.

“If both clinicians and people who may have arthritis remain stuck in the misperception that arthritis is an inevitable part of ageing and that there is nothing to be done to help manage the condition,” Dr Watt continues, “time may be lost in patients accessing essential treatment.”

Engaging with patients who have also visited their GP for advice, offers Dr Watt continual insight into where there are gaps in recognising symptoms of arthritis. She says: “Patients we’ve talked to do have an awareness that osteoarthritis is a disease that isn’t generally well-understood by both patients and some healthcare providers.”

She continues: “Healthcare providers would benefit from knowing the essentials: why osteoarthritis starts, why it gets worse in some people and not in others, why a joint is painful or swells, why the pain is better on some days, but not others. Having this knowledge



# The mechanisms that govern skeletal muscle function

In this second interview, Professor Dr Martin Flück reveals how his research aims to shed light on the mechanisms that govern skeletal muscle function in health and disease, with the goal of translating the findings into more effective clinical applications

To kick things off, Professor Dr Martin Flück explains how the research at the Laboratory for Muscle Plasticity at Balgrist University Hospital aims to shed light on the mechanisms that govern skeletal muscle function in health and disease, with the goal of translating the findings into more effective clinical applications. Martin notes that the approach of a head of a department is to make a patient-directed question that you must elucidate in a laboratory setting and he adds that the mechanisms in this respect need to be described in a coherent manner. This is because the words used to describe active processes when it comes to the muscle can be wrongly used and do not match what we would use to describe the biology of the patient. Martin then continues these themes in his own words, including the importance of accelerating translation for the benefit of the patient.

“We have been investing much in rediscovering older ideas – ones that surgeons originally rejected – based upon an incomplete description of the time course of muscle degeneration following a musculoskeletal injury. Previously, they looked at what happened in rotator cuff disease quite late in the degenerative process, which is quite common when a tendon ruptures, but much of the negative remodelling has already occurred at this point. As such, things have to be

checked early on which brings us back to a previous hypothesis that was rejected, Martin tells us. He goes on to expand this point in his own words.

“Basically, our approach is to translate the clinical problem in an experimental scenario that allows to test therapies for emerging bottlenecks in the recovery of musculoskeletal function of the patient. In this respect we now revisit early ideas for solutions of the negative remodeling of the injured muscle-tendon tissue composite which were set out 15 years ago, but rejected based on preliminary studies with negative outcome. We do this because we identify that the first window of opportunity for treatment after injury and reconstructive surgery, is short and not addressed experimentally, and consequently a number of active mechanisms were overlooked.

This can be explained for example by the destruction of the cellular powerhouse, mitochondria, with immobilization that was not considered important; but we now know now that this exerts a dominant negative influence on the maintenance of muscle mass and fatigue resistance. Based on these findings one can reasonably argue that the treatment of disuse-related aspects of musculoskeletal disease, such as after tendon rupture, should start early, before the deterioration of clinical

endpoints such as a loss in strength and fatigue resistance of muscle can be diagnosed and established as a chronic disability.

We also have a window of opportunity here to translate what we see in other muscle affections, such as during recovery from anterior cruciate ligament injury and repair and cardiovascular disease (CVD) that also involves the deconditioning of peripheral skeletal muscle (Flück et al, 2018). The critical factor here is how long the muscle is in a semi-stable state after an injury before it enters into a devastating spiral of muscle wasting. So, we aim to provide evidence in a coherent manner for how many days and weeks you can keep using the muscle before surgery needs to take place. We now know, for instance, when muscle loss occurs and when it transfers into fat.”

## **The power of medication and the importance of timing**

While it is not one of his main priorities, Martin then shares his thoughts on educating the patients in this respect, as a dentist would when advising that teeth should be brushed three times daily but if one does not follow such advice then things will go bad. When it comes to translation for the benefit of the patient, Martin believes that while very simple forms of medication are available, such as steroids, there are new drugs on the

market that have passed governmental tests, and as such, their use is safe for humans to ingest.

Martin's opinion is that the power of existing medication can be improved by timing when it is taken so that muscle deterioration can be delayed. For example, if medication is administered under neuromuscular electric stimulation during the first two weeks after injury when surgery typically does not take place because the patient is in a lot of pain and experiencing tissue swelling. This approach is the way forward, according to Martin, who adds that he works hard with the surgeons because they are not used to working in such a manner, so a rethinking of priorities is therefore essential when you have the first meeting with a patient.

## The benefits of excellent research facilities

The conversation then turns to explore Martin's thoughts on the superb new research facilities at the Balgrist Campus, and the benefit they have had on the valuable work and research at the campus. We find out how different parts of the Balgrist Campus are grouped together to enable easier access to research facilities and the pipelines are, therefore, tighter. In addition, there are other routines which allow for the acceleration of research because new investments have been made for the functional exploitation of muscle structure during movement.

Martin says that while his research output has not yet concretely benefited from the new facilities, interactions with other scientists who carry out anatomical measurements of the muscle has been a plus for him. "It is

much easier for the students or researchers to train using these methods to measure muscle volume, get a 3D image and analyse the muscle. The facilities are good because they are open during weekdays and the weekend so people can come in and get things turned around."

## State-of-the-art methods and technologies

This compelling interview continues, with Martin keen to detail the very important role that state-of-the-art methods and technologies play in the field of muscle research when it comes to the work taking place at the Balgrist Campus and in their fruitful cooperation with the Functional Genomics Center of the University of Zurich/ETH. Knowledge gathering can be accelerated, Martin reveals, in terms of exploiting paradigms in more breadth and in a higher resolution. State-of-the-art methods and technologies enable the measurement of multiple species and the use of powerful tools that enable researchers to work at a very fast pace. Still much work needs to be done in the field, Martin underlines.

"We still need good knowledge on the cell, biological, chemical and anatomical aspects of disease because it can be misleading to rely solely on results from one novel method. An image tool can always be used to draw conclusions about the raw numbers but nevertheless, combining that in a very elegant approach that relates to a systems biology that people advocate was raised at a conference around 11 years ago (Flück et al. 2008). "Now, we get biomarkers that allow us to screen patients out of the acceleration of numbers that we can relate to the relevant sizes of muscle, and we can

more easily determine something in blocks, for example, or by a simple genetic test."

## Personalised sports medicine and exercise rehabilitation

When it comes to disruptive ideas for personalised sports medicine and exercise rehabilitation, Martin says that one of his thoughts around this is the problem of getting economically viable pipelines established for medics. If it be for reasons of wisdom, or economic causes, the medical profession has typically been shy when it was to implement paradigm shifting approaches this demanded the reconsideration of established clinical routines. Now, it is about how a patient is aware of a problem and goes to a doctor to seek a solution. Sometimes, a doctor has a fair and good knowledge, but a researcher can be very well-informed about an aspect of health that perhaps a doctor doesn't know about. It might be that a doctor needs to do a literature search but although ultimately powerful and justified, this slows down decision taking. The latter in fact is a very active area of Research and Development in the Polytechnical School of Zurich (ETH) to identify faster and more comprehensive ways to approach a disease, Martin notes.

"Here, progressive methods could be used for other treatments even if it is not generally accepted nowadays. For example, if you had a bone fracture as I did, would you only do the training they tell you to do or would you do more, especially if you are experienced in physical training and know the limits of (your) human performance and capacity for the improvement through the stimulation of muscu-

loskeletal plasticity? Would you train hard to ensure a better recovery? Or do you want to get access to treatment that some people are using, such as biohacking that concerns legally allowed biological principles? For example, there are ways in which people can enrich their stem cells and reinject into them during training.

“Gene therapy won’t solve everything and when looking at this field of atrophy, it needs to be administered in doses because that is how we grow. We renew, or grow, our active muscles one by one, 1% every day. Using this method repeatedly is way too much for the health system, indeed, we don’t visit a doctor daily for two years, so we may anticipate to inject the agent in small doses. People who do biohacking reinject their stem cells when training daily for one month and then either stop or continue. This is not good for control and it is questionable if you carry this out in large numbers. But this is how these processes work. Improvements in strength and endurance rely on adaptations in muscle and tendons to (daily) repeated stimuli that if reach a specific threshold of mechanical or metabolic overload. The potency of it is enhanced by a high load of medication but the problem is that it uses far too many resources from the perspective of the health practitioner. Certainly, it is getting too expensive, so how do we deal with that? There will be big solutions to translate and in some cases, to abandon stem cell gene therapy for patients with many risks; but if it works, it will be quite disruptive. Martin then details his thoughts on rehabilitation after muscle injury occurs.

“Another more practical consideration is the contribution of the chiropractor or physiotherapist in rehabilitation. In the U.S., as the American Academy of Orthopaedic Surgeons sees it, the post-operative rehabilitation is conditioned by new ideas on the load, the intensity and volume of training. Physiotherapy often takes over that part but may overrule the researcher and possibly the orthopaedic surgeons because they have greater experience, and the pharmacist has even more experience of the drug.

“The well-trained physiotherapist is knowledgeable about rehabilitative interventions the patient should do post-operatively during musculoskeletal rehabilitation to achieve maximal benefit. The physiotherapist will do what is allowed in the window of intervention for the patient but maybe it could be done more aggressively and earlier? We have seen how in some hospitals in Germany, that certain post-operative interventions are starting much earlier to allow lymphatic drainage and reperfusion, for instance, after anterior cruciate ligament surgery. We know that this is very beneficial for healing from the experience of other surgeries as it is applied worldwide. So – this is something that we should actively pursue – that the physiotherapist or the people with knowledge of that aspect have more to say. This is the current practice of the American Academy of Orthopaedic Surgeons and hasn’t yet been fully carried over to larger parts of Switzerland.

“What is also a problem is that because there is an economic pipeline, defining within which duration post-operative interventions can be performed in a

hospital setting. New knowledge on therapeutic interventions which would extend beyond this window, or which are complicated to carry out in ambulant sessions of rehabilitation, may fall out of consideration for an implementation. This is particular concern for the reconditioning of an atrophied muscle, which must be tackled as early as possible by enhancing (or mimicking) the mechanical and metabolic load of an active muscle. There is a classic study from a famous English researcher which clearly shows that immediately after bone fracture, the contractile activity of concerned muscle groups must be increased for instance with sessions of neuromuscular electric stimulation (NMES) to maintain its protein balance.”

Martin adds that studies have been done around these aforementioned areas but they had not been carried out for a long enough duration to really gain benefit from. NMES may be used for some very high profile sports individuals, such as the number one acrobatic skier who has treatment at the Balgrist University Hospital and uses EMS for an hour or two daily which works. While there are not enough resources to understand how it works, the patient needs to be willing to do NMES for many months or years as shown successfully in rare cases of tetraplegic patients, Martin stresses, which is disruptive.

“I know of athletes using EMS at night and I know it works but there is a big disconnect between the basic knowledge and how you apply it. Only committed people use EMS, often externally through Balgrist University Hospital. The patient will stay in the



hospital for a month and this approach works but this method it is only disruptive if it is translated to all patients and the benefit for society would be great."

## The priorities for musculoskeletal disorders

Martin then sheds light on the priorities ahead for the diagnostics, treatment and rehabilitation of all musculoskeletal disorders. He says that his priorities for the future are very practical ones, in terms of the areas identified in this interview which need to be pursued. A willingness to change the system is needed, Martin notes and adds that if a treatment is available, it is important to ask at the Balgrist University Hospital with whom one can collaborate to apply such a genetic test. This involves much rethinking of the legal procedures when it comes to data protection and risk around genetic tests, Martin tells us.

In closing, Martin underlines that there is an issue today around health insurance because you cannot fully evaluate people in terms of numbers. Martin asks us to imagine that if we own a car and there is a problem with it then we go to the garage to get it repaired so that it works properly. This helps us to understand Martin's areas of research, and that Balgrist University Hospital sends out people who can walk again even though they may have a functional deficit following treatment but thresholds are not set to provide the patient with a map of the individual aspects of its musculoskeleton which require further improvement through therapy and training to empower a full regain of

functional work capacity. Martin develops this point and adds his concluding remarks to this in-depth interview.

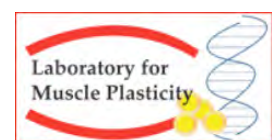
"Translating effective measures for the patient is a priority, so that they recover and that the form of treatment given is acceptable, such as gene therapy. Of course, gene therapy is far too expensive but the question is how can you do that? Do you have a risk priority in some areas? Or do you have the basic genetic tests that predict that such an approach will not help some patients, the health system or even the hospital?"

"The priority must be to substitute for a subtle, often unnoticed, genetic deficit with an effective treatment which is what we do in the cardiovascular field, where with a non-responder to rehabilitation we try to have another treatment that the patient can respond to.

"Finally, I want to add that I am not connected with my European colleagues who have two approaches. One is a centralised setting tied to the way the state is organised, such as in the UK, the Netherlands and Scandinavian countries that rely on an institutional monarchy who have specifically robust, but sometimes rigid, ways of tackling some diseases. But interestingly, there is a disconnect in terms of what we aim to do in Switzerland where we have a federal system to gather information and administer a solution in a totally different way.

"In the UK, for example, there are the state organs to indicate how to

pursue new treatments best based on a centralised database. In Switzerland, we gather information from our individual datasets and I see from my experience of working in different cultures that despite the possibilities for innovation provided by the latter approach, it sometimes lacks effective power for translation on a large scale. We need a solution to direct preventive and curative treatments in a more individual and economically viable manner to the entire spectra of the population. But to do so, we should combine a well-informed population-based approach with the innovative powers of an individualized approach, possibly by changing the organization of the health care system."



## The Balgrist

**Professor Dr Martin Fluck**  
Laboratory for Muscle Plasticity  
Balgrist University Hospital  
Tel: +41 44 510 7350  
martin.flueck@balgrist.ch  
<https://www.balgrist.ch/en/>



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# A FOCUS ON MUSCULOSKELETAL FUNCTION RESEARCH

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An interview with Professor Dr Martin Flück at the Laboratory for Muscle Plasticity at Balgrist University Hospital. Here he explains his fascinating research around musculoskeletal function, including the post-operation recovery of patients that have undergone surgery due to the rupture of a rotator cuff tendon.



by Chris Ross / Dreamstime.com

The **Balgrist**



# Hearing loss and the link with dementia

If we address hearing loss, can we really decrease our risk of developing dementia?

Mark Atkinson, Chief Executive Action of Hearing Loss investigates

**R**ecent global research suggests that hearing loss and dementia are linked. Having mild hearing loss is thought to double your risk of developing dementia and the level increases the more severe your hearing loss. So the risk is three times as great if you have moderate levels of hearing loss and five times as great if you have severe hearing loss.

Hearing loss is, therefore, one of the biggest risk factors for developing dementia but it is, potentially, modifiable – we might be able to decrease our risk of developing dementia by addressing our hearing loss. Research suggests that using hearing aids may reduce our likelihood of developing dementia. But we don't have definitive proof – more research is needed.

## Similar symptoms

The signs and symptoms of hearing loss and dementia are often similar – not responding when asked a question (or answering inappropriately), or struggling to understand sounds, including speech.

As a result, hearing loss is often misdiagnosed as dementia: people can receive inappropriate treatment for a condition they don't have, while their hearing loss goes unaddressed.

When someone does have dementia, unaddressed hearing loss can make it more difficult for them to cope – and may exacerbate dementia-related behaviour, such as aggression and anxiety.

Other evidence suggests that hearing loss is associated with a decline in memory skills, probably as the effort required from the brain to make sense of sounds is much greater. With hearing loss, the information about sounds that the brain receives from the ear is degraded – it may be muffled, or blurred and sounds at some

itches may not reach the brain at all, so it has to work harder to figure out what it's hearing.

This additional 'listening effort' reduces the resources that the brain has to do all the other things it needs to do and may accelerate or exacerbate cognitive decline. Cognitive decline is one of the hallmarks of dementia (but it's worth remembering that you can have cognitive decline without necessarily developing dementia).

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*"This year, in our International Project Grant scheme, we're asking researchers from around the world, who work in either hearing or dementia research, to send us applications for projects that aim to answer the questions above and help to uncover the link between hearing loss and dementia."*

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That's why more research is needed to clarify whether proper diagnosis and management of hearing loss, including providing hearing aids, may reduce the risk and impact of developing dementia.

## Need to know

But, although there are clear signs of a link between the two conditions, we don't really understand what that link is. We need research to tell us:

- Does hearing loss cause dementia? Or are both hearing loss and dementia caused by a different underlying factor, such as ageing? Could it be that they are actually completely unrelated and the increase in risk for dementia seen in people with hearing loss is simply coincidental (unlikely, but possible)?
- What is the actual link between hearing loss and dementia? What are the biological or cognitive processes that underlie these two conditions that could cause them to be linked?



*Mark Atkinson, Chief Executive Action on Hearing Loss*

This year, in our International Project Grant scheme, we're asking researchers from around the world, who work in either hearing or dementia research, to send us applications for projects that aim to answer the questions above and help to uncover the link between hearing loss and dementia.

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**"The signs and symptoms of hearing loss and dementia are often similar – not responding when asked a question (or answering inappropriately), or struggling to understand sounds, including speech."**

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Hopefully, the research we fund will help to answer some of these burning questions and bring us closer to ways to effectively confront the challenges we face in the future from the increasing global incidence of these conditions. ■

- Can treating hearing loss, for example, with hearing aids, reduce someone's likelihood of developing dementia, how fast it develops, or how badly it affects someone?
- Can we improve diagnostic tests for dementia and hearing loss, so that people aren't misdiagnosed?
- If there is a clear link between hearing loss and dementia, can we develop treatments to tackle both conditions?

To meet this challenge, we're working with Alzheimer's Research UK to co-fund research projects that will increase our understanding of the biological and cognitive processes underlying hearing loss and dementia.

**Mark Atkinson**  
**Chief Executive**

Action on Hearing Loss

Tel: +44 (0)808 808 0123

[information@hearingloss.org.uk](mailto:information@hearingloss.org.uk)

[www.actiononhearingloss.org.uk](http://www.actiononhearingloss.org.uk)

[www.twitter.com/actiononhearing](https://www.twitter.com/actiononhearing)

# Hearing speech in noisy environments

PhD students Courtney Coburn Glavin, Kailyn A. McFarlane, and Assistant Professor Jason Tait Sanchez discuss the mechanisms, barriers, and future progress for hearing speech in noisy environments

**W**hen you find yourself struggling to hear in a noisy restaurant, chances are you aren't alone. Difficulty understanding speech-in-noise (SIN) is one of the most common hearing-related complaints<sup>1</sup>. This problem is not unique to individuals with clinically defined hearing loss; estimates suggest that as many as 26 million people complain of hearing difficulties in noisy situations despite having clinically "normal" hearing<sup>2</sup>. Even with renewed attention to this problem in the fields of audiology and hearing science, its etiology, and thus, diagnosis and treatment in humans remains elusive.

In this research profile we: 1) explore potential mechanisms underlying this phenomenon, 2) consider barriers to validating and identifying this problem, and 3) discuss our lab's novel approach to this problem.

## Potential mechanisms

Cochlear synaptopathy – a term used to describe synapse damage and loss between inner hair cells of the cochlea and auditory nerve fibers – has been demonstrated to occur after noise exposure in animal models<sup>3,4,5</sup>. This form of hearing impairment is termed "hidden" hearing loss because traditional tests of hearing integrity are not sensitive enough to detect this synaptic disruption. Some theorize that synaptopathy could explain SIN deficits in humans, given that it occurs after auditory insult and is a deficit "hidden" from traditional hearing tests.

However, the presence of synaptopathy following noise insult is not ubiquitous, even in animal models<sup>6</sup>. Results in humans are further complicated by the fact that synaptic damage cannot be directly verified because of the invasive nature of doing so. Many studies, using proxy measures of synaptopathy, have failed to find systematic evidence of this pathology in humans<sup>7,8</sup>. This could be due to the inability to directly measure the phenomenon, the lack of experimental control in exposing humans to environmental insults, or the true absence of synaptopathy in humans. Based on existing evidence, synaptopathy is likely not the sole explanation for SIN deficits in humans.

Hearing loss in frequency regions not typically evaluated with traditional hearing tests has also been suggested as a reason for SIN difficulty. Though the range of human hearing extends up to 20,000 Hz, traditional hearing tests evaluate frequency sensitivity only to 8,000 Hz. Testing higher frequencies is time-consuming and there are equipment limitations in presenting high frequency stimuli. Both of these factors have resulted in a significant portion of the human hearing range left unevaluated.

This dilemma is important because the cochlea of the inner ear is frequency-tuned (i.e., tonotopic); specific regions are most sensitive to high frequency sounds, while other regions are most sensitive to low frequency sounds. The region sensitive to higher frequencies

is also believed to be most susceptible to environmental insult, making the relationship between high frequency hearing loss above 8,000 Hz and SIN difficulties conceivable. More research in this area is needed to better understand this potential relationship.

## Limitations to validation and identification

A major barrier to identifying SIN difficulties in humans is the shortage of diagnostic tests that are sensitive enough to evaluate the integrity of specific anatomical locations within the complex auditory pathway. This prevents us from obtaining a clear picture of functional and structural changes that occur with age or environmental insult. The traditional test of hearing is the behavioural audiogram. Though it is the current gold standard for assessing auditory function, it is a gross measure of hearing.

While the health of some anatomical sites of the auditory pathway can be reliably assessed through existing diagnostic tools (e.g., integrity of outer hair cells is thought to be captured by measures of otoacoustic emissions), others, such as inner hair cells, cochlear synapses, and more central structures cannot be assessed and interpreted in a straightforward manner in humans.

For example, Wave I of the auditory brainstem response (ABR) is thought to reflect the integrity of the synaptic connection between inner hair cells and auditory nerve fibers. However,



studies investigating the use of Wave I as a biomarker for functional SIN deficits have yielded mixed results in humans<sup>9,10,11</sup>.

The clinical use of diagnostic measures beyond the audiogram is another problem in characterising SIN deficits in humans. Fewer than 15% of audiologists report routinely assessing SIN performance in their patients<sup>2</sup>. Even when used clinically, existing SIN tests are highly variable and may not assess the same constructs.

For example, some SIN tests use speech babble as background noise, whereas others use steady-state noise; some use an adaptive procedure that changes based on performance, whereas others use a fixed procedure. Thus, some SIN procedures may not accurately reflect real-world listening situations, and their variability limits cross-study comparisons of patient performance. This limits reliable identification of SIN problems and their relationship to other measures of hearing.

## Future progress

Ultimately, the largest barrier to identifying the etiology of SIN deficits lies in the complexity of the human experience. Over the course of a lifetime, a person is exposed to an amalgamation of environmental insults, each of which interact with the person's genetic makeup. Mechanisms underlying problems with SIN are multifaceted in nature and are likely more complex in humans than other animals.

"Sound conditioning" and "toughening", for example, are ideas that previous noise exposure leads to reduced susceptibility of the auditory system to noise<sup>12,13</sup>. Individuals who have a history of noise exposure may then be less vulnerable to future auditory insults. Sound conditioning has been

proposed as one explanation for the mixed evidence of SIN etiology and difficulties in humans.

The research conducted in the Sanchez Laboratory at Northwestern University takes a unique approach to examining SIN deficits in humans. Specifically, we compare individuals with self-reported SIN deficits to those with no reported SIN issues on an extensive battery of auditory diagnostic tests. In this way, we do not rely solely on objective measures of SIN ability, which are highly variable and may not reflect real-world experiences.

From our extensive test battery and large pool of participants, we hope to identify clinically viable measures that validate patient complaints and are sensitive to the underlying mechanisms behind SIN deficits. Given the number of individuals who experience SIN-related problems, there is a tremendous need to improve their communication abilities. Treatment options, however, cannot fully be explored until we understand the etiology of this issue and can reliably validate and identify it in humans.

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## Affiliations:

The Roxelyn and Richard Pepper Department of Communication Sciences and Disorders.

The Department of Neurobiology.

The Hugh Knowles Hearing Research Center. Northwestern University. Evanston, Illinois, 60208, USA.



**Northwestern  
University**

**Courtney Coburn Glavin, Au.D., FAAA  
Ph.D. Student**

Northwestern University

Tel: +1 847 467 0123

CourtneyGlavin@u.northwestern.edu

**Kailyn A. McFarlane**

**Au.D./Ph.D. Student**

Northwestern University

Tel: +1 972 832 8744

KailynMcFarlane2023@u.northwestern.edu

**Jason Tait Sanchez, Ph.D., CCC-A, FAAA  
Assistant Professor**

Northwestern University

Tel: +1 847 491 4648

Jason.sanchez@northwestern.edu

<http://caplab.northwestern.edu/>

# Wise healthcare spending can deliver better outcomes

Barbara Harpham, Chair of the Medical Technology Group, wants to see healthcare spending, particularly on medical technology, linked to tangible outcomes for patients, the economy and society

In June 2018, the UK Government announced an additional £20 billion in healthcare funding for England's National Health Service. The cash injection – in the year that the service celebrated its 70th anniversary – was warmly welcomed. The additional funding represented a 3.4% increase in the NHS's budget in real terms over the next five years, meaning that although England still lags behind some Western European countries in terms of healthcare spending, the gap has narrowed.<sup>1</sup>

Following that announcement, Secretary of State for Health Matt Hancock outlined his vision for a health service that uses technology to 'improve our health, make our lives easier and make our money go further'. His proposed strategy includes greater use of cutting edge mobile and IT solutions.

**“Moving to a new payment system linked to patient outcomes and societal benefits will ensure we fund more of the treatments we need to keep the population healthy and able to work for as long as they need to.”**

These ambitions are laudable, but there is a danger that much of the investment could go to waste unless the health service takes a close, hard look at the way it currently procures products and services, taking into account the impact on patient outcomes and the potential savings to the healthcare system. It also needs to consider the broader economic and societal value to ensure that additional spending contributes to a healthcare system that is sustainable for future generations.

## **Better investment means a better society**

Just over \$7.8 billion of public healthcare spending in England – approximately 5% of the total annual budget – is spent on medical technology. Medical devices, of

which there are around half a million – from in-vitro diagnostics, to implantable devices and e-health – play an enormous role in delivering better healthcare. They have a tangible impact on patient outcomes and healthcare budgets, often preventing the need for further treatment and hospital stays while enabling people of working age to return to the workplace.

The Medical Technology Group, in association with the Work Foundation, has studied the impact of MedTech closely. In our report ['Keeping Britain Working – How medical technology can help reduce the cost of ill health to the UK economy'](#) – published in November 2017 – we reported that the impact of sickness, absence and worklessness associated with working age illness costs the UK economy over \$130 billion a year. Meanwhile, individuals collectively miss out on \$5.2 billion a year of lost earnings and over 300,000 people take up health-related benefits.<sup>2</sup>

The report assessed the impact of eight technologies in reducing the need for further treatment and hospitalisations, limiting welfare and social security payments, as well as returning individuals of working age to employment as tax-paying members of society. It also explored benefits, such as improved quality of life for patients and the impact on the growing number of unpaid carers, who are able to return to work or contribute to society in other ways.

The study concluded that \$618 million in savings could be generated in reduced long-term health costs and benefit payments from these eight technologies alone. An extra \$1.3 billion – or 5% of the UK's additional healthcare funding spent on valuable medical technologies – could, therefore, generate even greater savings for the wider economy, in terms of reduced healthcare costs, lower welfare spending and increased tax revenues.

### Focus on value-based commissioning

This vision for a future healthcare system where medical technology delivers its full potential is only achievable if the new cash injection by the UK Government is accompanied by a thorough review of healthcare spending.

For example, the current approach of buying the cheapest possible products urgently needs to be reformed. Instead, buyers and commissioners should ensure that value-based healthcare linked to desired outcomes becomes a key component of the payment system. This fundamental shift is needed to ensure value for the tax-paying public, the sustainability of the health service and access to the most appropriate medical technologies for patients.

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**"Rather than rationing access and reducing commissioning budgets, efficiency drives should focus on increasing the provision of cost-effective treatments."**

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### Rationing and delays are not the answer

Moving to a new payment system linked to patient outcomes and societal benefits will ensure we fund more of the treatments we need to keep the population healthy and able to work for as long as they need to. It will also help create a health service that is at the forefront of medical technology access and adoption for the next 70 years.

Meanwhile, rather than rationing access and reducing commissioning budgets, efficiency drives should focus on increasing the provision of cost-effective treatments. Health services must not confuse limiting access to healthcare with prudent decision-making.

Rationing, as exposed by the MTG's recent [Ration Watch campaign](#), is not a solution and delaying treatment only results in increased costs and poorer outcomes for patients in the long run.<sup>3</sup> It also means that as a society we miss out on the enormous benefits of early intervention and rapid return of patients to their daily lives and activities.

### A chance to lead the world in health

Additional funding in healthcare by national governments presents an enormous potential opportunity, not just for health services and individual patients, but also for wider society.

However, investment must be accompanied by radical reforms to the way the system operates. It needs a change in culture and practice and a joined-up approach that considers the broader impact of the investment.

Only then will we see the full impact of medical technology. ■

The [Medical Technology Group](#) is a not-for-profit coalition of patient groups, research charities and medical device manufacturers working together to improve patient access to effective medical technologies.

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### Barbara Harpham Chair

Medical Technology Group  
[mtg@mailpbconsulting.com](mailto:mtg@mailpbconsulting.com)  
<https://mtg.org.uk/>  
[www.twitter.com/MedTechGroup](https://twitter.com/MedTechGroup)



# Cardiovascular magnetic resonance imaging and spectroscopy

Beyond imaging, cardiovascular magnetic resonance techniques can be employed to unveil metabolic alterations preceding anatomical and functional manifestations of (cardiovascular) diseases, as the Department of Experimental Cardiovascular Imaging in Germany explains here

As has been pointed out previously, the tremendous amounts of hydrogen ( $^1\text{H}$ ) present in the water ( $\text{H}_2\text{O}$ ) of our body allow a superb illustration of the cardiovascular anatomy by magnetic resonance imaging (MRI) – even in miniaturised experimental mouse models which are used to mimic and explore human diseases. However, beyond morphology, magnetic resonance spectroscopy (MRS) can also be exploited to address important metabolic processes, which are mandatory for the proper function of the heart (and also all other organs).

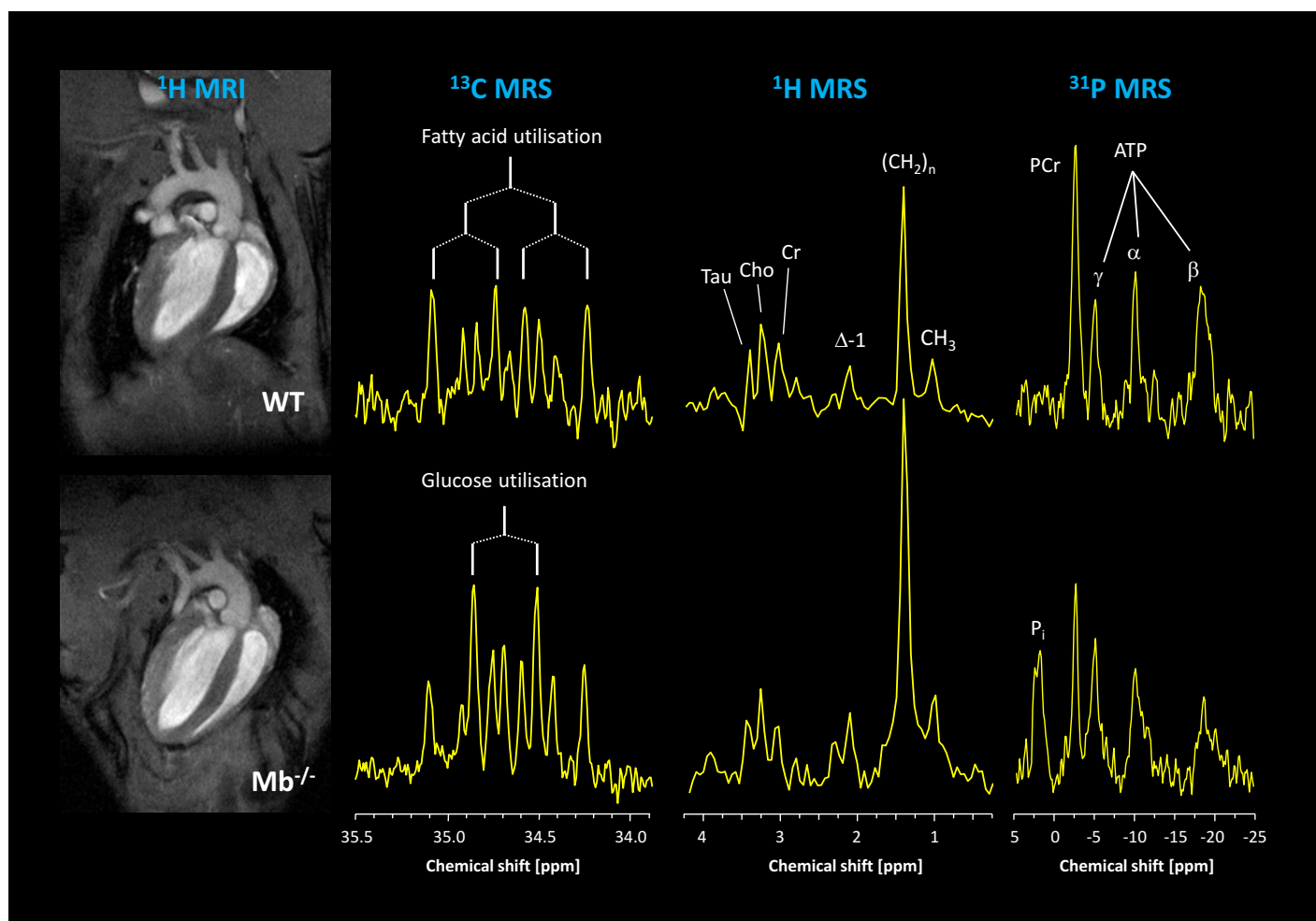
To ensure the continuous energy supply required for regular heart work, a permanent *de novo* synthesis of the spent ATP – the most important energy carrier within the body – is essential. For this, primarily sugars and fatty acids are burned, e.g. glucose and palmitic acid. The healthy heart usually fuels its energy production by one third from glucose and by two-thirds from fatty acid oxidation. However, in several cardiac diseases – in particular, under conditions of limited oxygen support – this normal ratio is shifted to increased glucose utilisation and reduced oxidation of fatty acids. Such substrate shifts can be smartly demonstrated by isotopomer analysis using  $^{13}\text{C}$  MRS. To this end, the heart is supplied with substrates, at which the normal carbon isotope  $^{12}\text{C}$  is substituted at suitable positions in the molecule by the naturally to less than

1% abundant isotope  $^{13}\text{C}$  (in contrast to  $^{14}\text{C}$  not radioactive). When these substrates are running through the normal metabolic pathways, the  $^{13}\text{C}$  labels of glucose and palmitate will end up at different positions of the glutamate carbon skeleton depending from the original substrate, as well as the number of turns within the citric acid cycle. The differing neighbourhood of  $^{13}\text{C}$  nuclei in the respective glutamate isotopomers is then reflected in individual  $^{13}\text{C}$  MRS coupling patterns, which allow an unequivocal assessment from which carbon source the individual isotopomers originate and, thereby, alterations in substrate metabolism can easily be detected.

This is illustrated in a model of hindered oxygen delivery to the myocardium caused by lack of the hemoprotein myoglobin. While morphology and function are equal in normal, healthy mice (1<sup>st</sup> column; top, WT=wildtype) and mice lacking myoglobin (bottom, Mb<sup>-/-</sup>), it is striking that  $^{13}\text{C}$  MRS coupling patterns clearly differ (2<sup>nd</sup> column). When comparing these signals with a coupling scheme shown here, it becomes evident that in the upper spectrum the signals pointing to the utilisation of palmitate are particularly eye-catching, while in the lower trace the patterns evoked by combustion of glucose stick out. The quantitative analysis reveals that lack of myoglobin leads to a shift of the normal fuel utilisation ratio of 1:3

(glucose: palmitate) to an almost equal metabolisation of both substrates – a shift which is similarly observed in humans with cardiac hypertrophy, i.e. an overgrowth of the heart resulting in increased diffusion distances and limited oxygen transport.

In the present model, the detected substrate shift obviously acts as a biochemical oxygen saving mechanism at the consumer end: it is well known that for combustion of glucose noticeable less oxygen is required as for fatty acids – at a generation of same amounts of ATP. Therefore, by increased utilisation of the oxidative more favourable substrate, that is glucose, myoglobin-deficient hearts can compensate for the limited oxygen supply. While in young mice, this helps to ensure uncompromised cardiac function, in the long run this substrate switch leads to serious side effects, in that the permanent preferred utilisation of glucose leads to an enhanced accumulation of lipids in older Mb<sup>-/-</sup> hearts. This is demonstrated in the third column showing  $^1\text{H}$  MR spectra acquired from the interventricular septum. Here, resonances for creatine (Cre), taurine (Tau), choline (Cho) and several signals originating from lipids ( $\Delta-1$ ,  $(\text{CH}_2)_n$ ,  $\text{CH}_3$ ) can be unequivocally resolved. While signals for the first metabolites are comparable, all lipid peaks are substantially increased in hearts lacking myoglobin. Quantification revealed that Mb<sup>-/-</sup> hearts are



characterised by a threefold higher lipid content compared to WT. This disparity was not apparent in younger mice pointing to a chronic response to the altered substrate utilisation.

Importantly, increased long-term accumulation of lipids is known to result in an enhanced formation of reactive oxygen species and to dysregulation of mitochondrial function which is crucial for resynthesis of ATP. This molecule can be excellently detected by  $^{31}P$  MRS – each of its three phosphorus atoms ( $\alpha$ ,  $\beta$ ,  $\gamma$ ) yields a unique signal (4<sup>th</sup> column). When this approach is applied to myocardial energetics of older  $Mb^{-/-}$  mice, it becomes evident that the prolonged lipid accumulation indeed leads to compromised energy homeostasis. The comparison of  $^{31}P$  MR spectra of  $Mb^{-/-}$  and WT hearts clearly demon-

strates substantially lower myocardial phosphocreatine (PCr) levels for the mutant, reflecting a limited availability of this 'energetic buffer' as a consequence of the chronically altered metabolism. It is noteworthy, that the extent of the observed energetic deterioration in this mouse model is of similar magnitude as the alterations determined in humans during the development of heart failure.

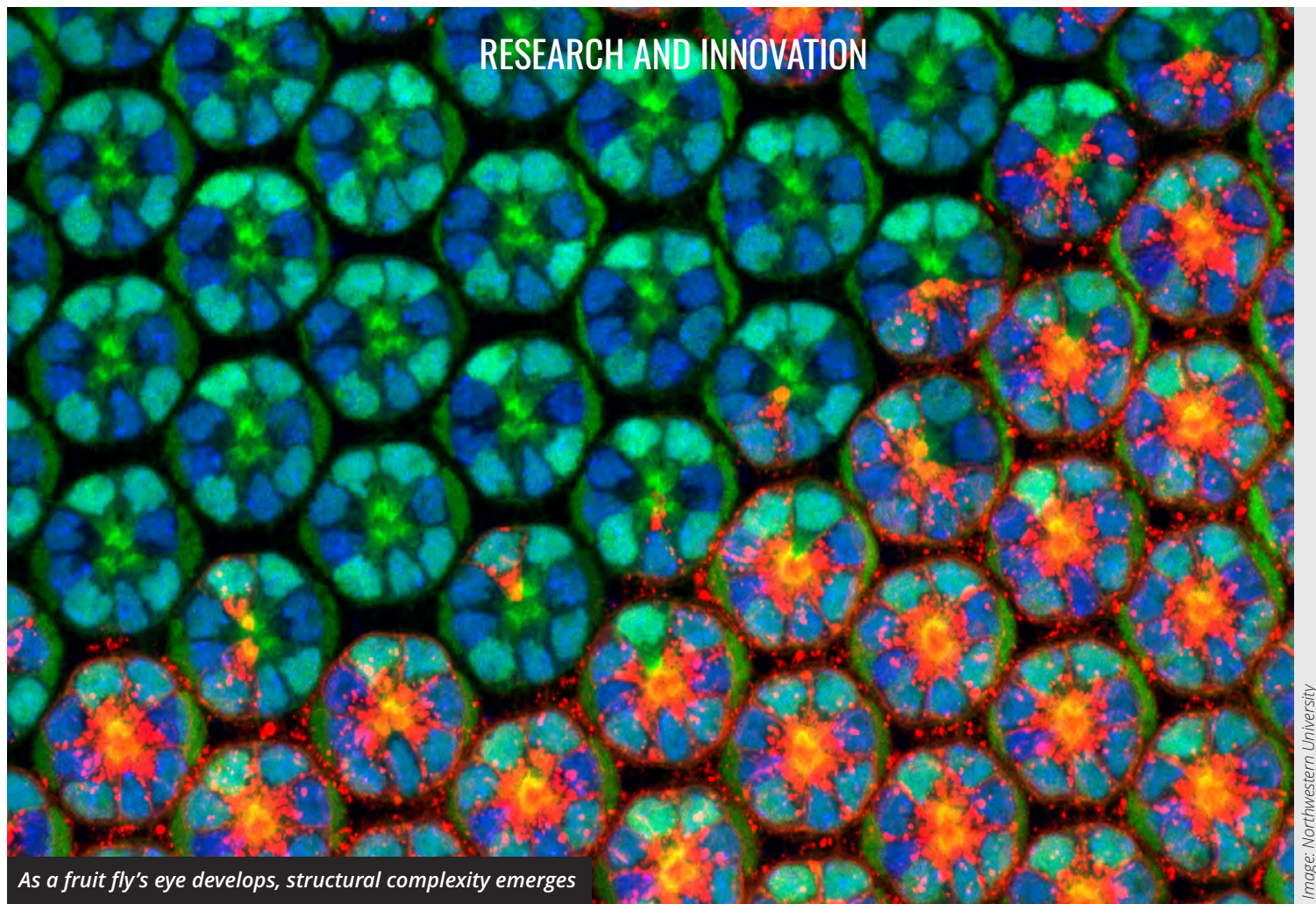
As shown by these examples, the combined use of several MRS techniques allows to gain a comprehensive picture of heart metabolism and energetics – already at a time point when no anatomical and functional manifestations yet occur. Due to the non-invasive nature of these investigations, repetitive measurements can serve to monitor the progression of heart diseases and to assess the

success of suitable therapies in both (i) experimental models for the exploration of the underlying causes of human cardiomyopathies and (ii) humans for diagnosis and adjustment of personalised precision medicine.

*Heinrich Heine*  
HEINRICH HEINE  
UNIVERSITÄT DÜSSELDORF

**Ulrich Flögel**  
**Professor of Experimental**  
**Cardiovascular Imaging**  
Heinrich Heine University Düsseldorf,  
Germany  
Tel: +49 211 8110187  
floegel@uni-duesseldorf.de  
www.nmr.hhu.de





*As a fruit fly's eye develops, structural complexity emerges*

Image: Northwestern University

# Bringing mathematical perspectives to the biological search for the Rules of Life

Editor of Open Access Government, Jonathan Miles, spoke to Juan Meza at the National Science Foundation about the launch of four new centres to bring mathematical perspectives to the biological search for the Rules of Life

The National Science Foundation (NSF), in partnership with the Simons Foundation, in May 2018, launched four new centres to bring mathematical perspectives to the biological search for the Rules of Life. Collectively, the centres will produce a new generation of scientists equipped to tackle questions that cannot be answered today.

The NSF-Simons Research Centers for Mathematics of Complex Biological Systems aim to explore how information encoded in DNA results in complex organisms with diverse forms, functions and behaviours when it is manipulated by changing environments across multiple time scales.

The NSF-Simons Centers will enable scientists to understand, with unprecedented clarity, how genes translate into so many diverse phenotypes. This endeavour will help the NSF address one of its [10 Big Ideas, Understanding the Rules of Life: Predicting Phenotype](#), which explains how the Rules of Life are expressed across many scales of structure and time.

In this question and answer interview with Juan Meza at the National Science Foundation (NSF), we learn that such knowledge may lead to a predictive framework for understanding the pathways that lead from the DNA within a cell to the myriad expressions of an organism in its environment. We also discover that



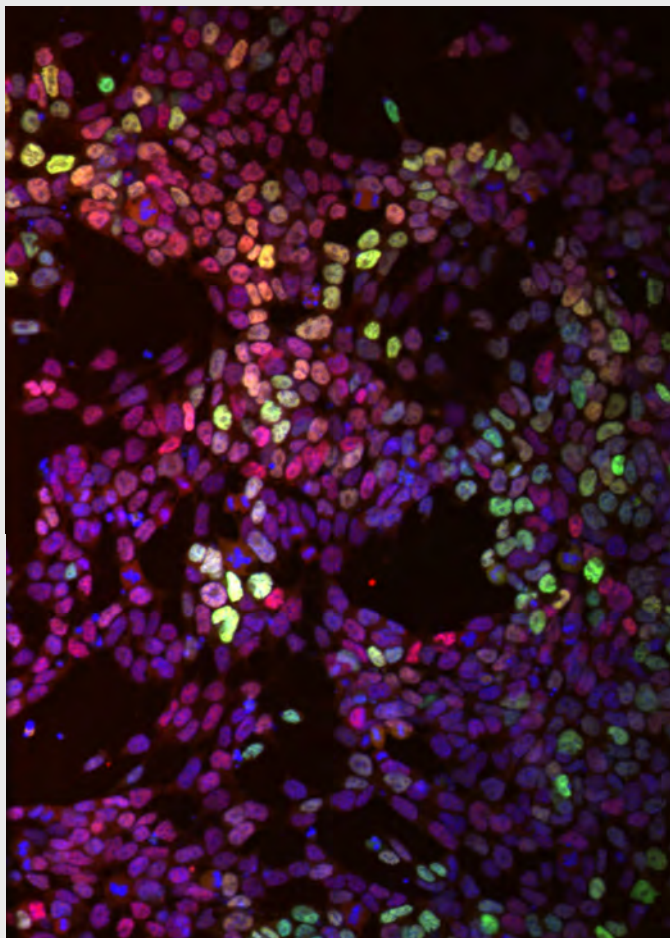


Image: Georgia Tech/Melissa Kemp

*Gene expression and cell decisions guide stem cells (green) into differentiated cells (red). Researchers at Georgia Tech are studying how basic stem cells become specific cells in the body based on which genes are expressed and other cellular decisions*

maths is more than just proofs or calculations but is a really powerful tool that helps us study nature.

**Thank you for taking the time to speak to me today. First, tell us how the National Science Foundation (NSF), in a partnership, has launched four new centres to bring mathematical perspectives to the biological search for the Rules of Life?**

The partnership came about through a lot of discussions, both internally and externally. We had a workshop here at the NSF and we followed that up with discussions with other parts of the organisation. Throughout these discussions, we realised that we had reached a tipping point at which the combination of mathematics, data and biology could have a big impact on our understanding of biological processes. Thus, we came up with a couple of goals, the first of which was to enable

innovative and collaborative research at the intersection of mathematics and three different areas of biology: molecular, cellular and organismal.

A secondary goal was to establish new connections between the two disciplines and to promote the interdisciplinary education and workforce training that we felt was needed to proceed in the field.

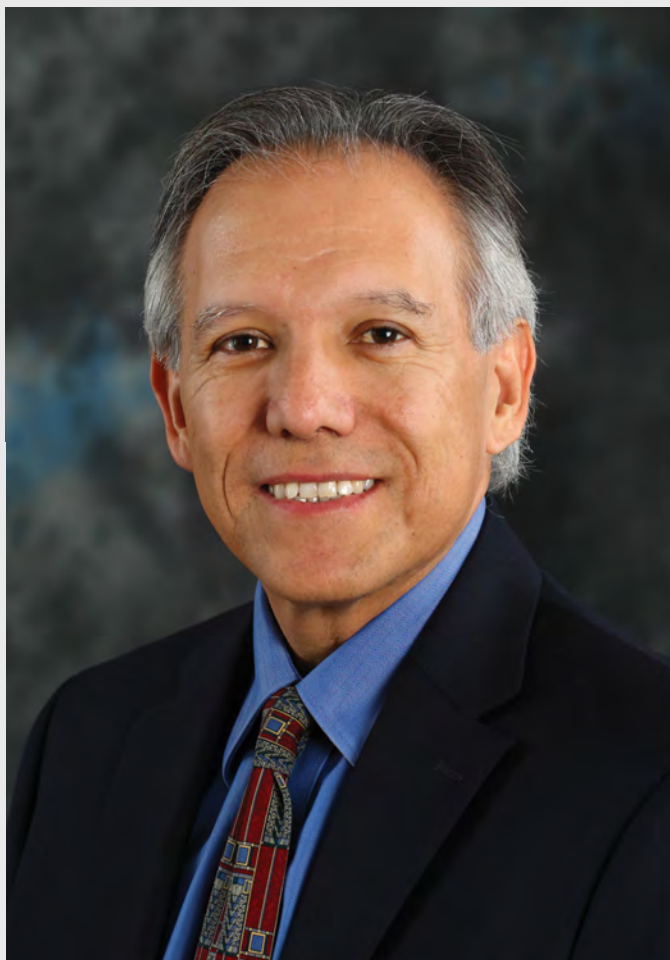
**Thank you for that very interesting answer. What kind of knowledge will the centres explore and what could this lead to, for example, a predictive framework for understanding the pathways that lead from the DNA within a cell?**

The main focus is to explore the interface between mathematics and biology. All the centres are going to be involved in trying to develop a better understanding of these thought processes because they are very complex and involve the entire spectrum going from the genotype to the phenotype. But each centre is going to have a goal or a specific set of goals that are all slightly different.

For example, The NSF-Simons Center for Multiscale Cell Fate Research at the University of California, Irvine, will look at what determines cell fate – the differentiation of cells into specific biological cell types. The best way to describe it is to say, “well, how do individual cells develop into specific types of tissue?” So you start with a single cell and then after a while, you have a liver cell, a heart cell or a muscle cell - how does that happen? We know that these cells receive signals from other cells and that will tip them off and let them know that they should be doing certain things. But how, when and where these signals occur is still something of a mystery.

**Many thanks for this insight. Now, I am very intrigued by your comment that “many people think of math as proofs or calculations, but it’s so much more” and wondered if you could develop this thought when it comes to applying mathematics to the complex processes that underlie biology?**

I sometimes get a laugh out of this because I think that many of us develop a maths phobia and what we remember is that in this subject you need proofs. For



Juan Meza, Director, Division of Mathematical Sciences

example, think back to when you took Geometry and wanted to show that one triangle was the same as another one. That was a sort of proof that we had to come up with. Or sometimes we think in terms of algebra, so, many of us dreaded the old question of, “how do you solve this quadratic equation?” We’re given these formulas and calculations – that’s what we think of when we think of maths. But I like to think of it as something completely different in that maths’ power really comes in because we can develop models and use them for both describing and predicting things. What that does, is that it allows us to really understand complex processes.

We state the problem in terms of mathematics – that’s the first step but then that allows you to bring in literally hundreds or maybe even thousands of years of knowledge to bear on the problem. And it allows us

today to provide accurate weather forecasts. It allows us to provide links between environmental and genetic factors and certain diseases. Each of us uses maths every day whenever we make a phone call or make a purchase online – using number theory to encrypt your messages back and forth.

Now in biology, it’s slightly different in the sense that there are a lot of processes and mechanisms that are very complex, but they lend themselves easily to mathematical modelling. In the example I just gave with the cell fate, you could model how a signal is sent from one cell to another. And then you want to see how these signals are interconnected with a network of cells. You might think of it in the same way you might model electricity by moving it through the power grid. Essentially, it is the same kind of mechanism.

Here, the applications are really quite different. But the mathematics is quite similar so that that gives us the power of the maths to be able to apply it to many different applications, some of which are very complex.

### **Tell us how the centres will build research capacity at the interface between mathematics and biology through cross-disciplinary training of students and postdoctoral associates, for example.**

I’m really excited about the training of a new generation of researchers and the young folks who could come in and work well in both worlds – in biology and mathematics. I think it’s too easy to spend all of our time in one small part of our research but I predict the future major advances are going to occur at the interface of the scientific disciplines, for example, in maths and biology. That’s why I think it’s important to train the next generation of researchers because we want them to be able to work in multiple disciplines and to be able to talk across these different disciplines. That’s where the core of the new ideas will be coming from.

### **As an example of the four centres, tell us about the aims of the NSF-Simons Southeast Center for Mathematics and Biology and how they will address how genetic information impacts phenotypic traits.**

We want to develop an interdisciplinary collaborative

team to model these complex biosystems. This centre is actually a little different than the other ones. What they propose is to have seven different projects and each of them will have a pairing so there will be one biosystem experimentalist working side by side with one mathematician. And each team will look at a particular problem in the genotype to phenotype landscape. Just to give you one example, one of the things we're going to look at is why that phenotype is consistent despite variations in both genotype and the environment. In other words, why is biology so robust? But we have a genotype, and depending on the environment, it will do a certain thing.

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**"I'm really excited about the training of a new generation of researchers and the young folks who could come in and work well in both worlds – in biology and mathematics. I think it's too easy to spend all of our time in one small part of our research but I predict the future major advances are going to occur at the interface of the scientific disciplines, for example, in maths and biology."**

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You can look at the example of the development of a stem cell to a muscle cell – the environment is not the same each time this happens yet we always get the same result at the end. Somehow biology and life have managed to develop a system that despite many differences in the environment, we still end up with a fairly robust system that tends to give you the same result after many instances.

### **How will the NSF-Simons Centers enable scientists to understand, in unprecedented clarity, how genes translate into so many diverse phenotypes?**

I'd like to point out that there have been some incredible advances in technology during the last 10 or so years. And it has completely changed how we address biology problems. If you take a look at, for example, gene sequencing or new imaging technologies that led to having access to unprecedented amounts of data, much of which is very high-quality data. We're able to get sequencing on single cells at this point and we have incredible detail on imaging. So that sort of points out and there is a lot of information here but how do we take advantage of this wealth of data?

What we believe is that by combining the data with the mathematical models, such as the ones that I mentioned earlier, it's going to allow us to develop predictive models. These models will have been validated with real data, so what that allows us to do is to then be able to predict certain things and then we can go back and check them. The models will help us understand where we might look for more detail. That will allow us to go back and do more experiments and fill in the gaps and that means a more accurate and more predictive model. It is a cycle, in fact, that gives us more and better models and higher-quality predictive models.

### **Is there anything you would like to add?**

Well, first of all, thank you for the opportunity to talk with you. I think it is wonderful to share our exciting results but I would like to add that we're only at the beginning of an incredible and really important journey. Nobody knows how this is going to play out but I think the potential for revolutionary advances in biology is tremendous, especially when it's coupled with mathematics and all of the data that we have. ■

#### **Juan Meza (interview)**

##### **Director**

Division of Mathematical Sciences

Directorate for Mathematical & Physical Sciences (MPS)

National Science Foundation

Tel: +1 (703) 292 8870

[www.nsf.gov/dir/index.jsp?org=MPS](http://www.nsf.gov/dir/index.jsp?org=MPS)

[www.twitter.com/NSF](https://twitter.com/NSF)



# Chasing the e-commerce market: The Omni-channel revolution

Experts from the Indian Institute of Management Ahmedabad, and the University of Michigan share their thoughts on the Omni-channel revolution

To quote the State of Retail Supply Chain Report (SRSCR) 2018: “This is the most dynamic era in retailing and the only constant is change.” There is no doubt that e-commerce will continue to shape retailers’ strategic and tactical decisions in the coming years. In 2018, U.S. e-commerce sales hit more than \$500 billion – an increase of about 15% from the previous year – and accounted for about 14% of the total U.S. retail sales. These strong indicators have not been confined to the US only. The global e-commerce sales in 2018 were almost \$3 trillion – an increase of about 18% from the prior year – and accounted for about 15% of the total global retail sales. It is projected that e-commerce sales will continue to grow and reach a 17% share of total retail sales within the next few years (in contrast, U.S. e-commerce sales a decade ago was only 6% of the total U.S. retail sales).

The message is clear: E-commerce growth is real, not just a passing fad. Since a significant portion of the growth in retail sales is expected to come from e-commerce purchases, retailers need to master a sound e-commerce strategy to remain competitive in the market. The execution, however, is not easy. Thanks to the so-called Amazon effect, consumers nowadays are used to an easy online shopping experience and a quick delivery. Alas, providing such a high level of shopping experience is



extremely costly! This has motivated retailers to experiment with new approaches, collectively dubbed as the omni-channel strategies. Some failed, some survived and those who survived continued to improve and innovate.

## **Classic omni-channel: Strategies and challenges**

Consider, for example, the challenge of satisfying consumer expectation of quick delivery. Unless you are a giant e-commerce retailer, such as Amazon, you most likely do not have either the right scale or infrastructure to operate as cost-efficiently as Amazon in the quick-delivery space. If your customer is located far from your nearest warehouse, it could take a few days for his or her package to be delivered. What’s the alternative? One way is to fulfil e-commerce orders directly from a

brick-and-mortar store near to the customer, which can cut down the delivery time to at most two days.

Another option is the so-called Buy-Online-Pickup-In-Store (BOPIS, or click-and-collect), which was first introduced by John Lewis, a UK-based chain of a high-end department store, in 2007. BOPIS has since been widely adopted by many retailers worldwide and is nowadays considered a standard strategy of omni-channel fulfilment.

In addition to ship-from-store and BOPIS, there are plenty other omni-channel strategies that focus on improving the customer shopping experience such as Buy-Online-Return-In-Store (BORIS), ship from one store to another store, locker pick-up, curbside pick-up, etc.

While the idea behind many omni-channel strategies is intuitive, their implementation can be quite challenging. Consider again the ship-from-store fulfilment strategy. To implement this, retailers need to first have real-time inventory visibility across all stores. Sadly, some retailers still work with a legacy system that does not provide them with the necessary visibility. Secondly, since store inventories are now used to fulfil both in-store and online demands, retailers need to improve their forecast accuracy. The inaccurate forecast may lead to unfavourable business scenarios: either too much inventory in stock, resulting in high in-store carrying cost or too little inventory causing high stock-out rates. In the word of one of the respondents of SRSCR 2018, "You need the right balance of inventory to support both the omni-channel experience and the in-store experience. To succeed, it would take a different way of thinking about demand forecasting than how we've viewed it in the past." But, forecasting is not easy either. Some retailers need to come up with forecasts of not only a single product but at least a few hundred thousands of products and sales data is not always abundant. Finally, retailers also need to optimise their fulfilment decisions. Although fulfilment from the closest store seems intuitive, it is not always optimal because it ignores future demand forecasts and inventory distribution across all stores.

## Looking into the future: The challenge of urban logistics

At the time when Amazon was born in 1994, little did the rest of the world know that retailing as we knew it will forever be changed. Today, some of the most sophisticated quantitative methods are being developed and applied to solve retail problems on a daily basis, all in the name of meeting consumer

expectations. While the last decade has witnessed the transformation of many retailers into so-called omni-channel retailers, the next decade is likely to see a more intense transformation and competition closer to home.

**"The message is clear: E-commerce growth is real, not just a passing fad. Since a significant portion of the growth in retail sales is expected to come from e-commerce purchases, retailers need to master a sound e-commerce strategy to remain competitive in the market."**

As reported in<sup>1</sup>, in New York City alone, there are 10 million people within a 20-mile radius of the Empire State building who spend a total of about \$20 billion every year on e-commerce purchases. It is also reported that 64% of online consumers expect orders placed by 5 pm to qualify for same-day delivery. Imagine the possibilities if retailers could tap into this consumer segment. But, implementing urban fulfilment is not easy. While labour availability and last-mile delivery costs are no longer issues in a big city, stores in a highly populated city have a much smaller storage space, which requires more careful inventory planning. In addition, there are many limiting city infrastructures such as limited parking area and stop times, restrictions on vehicle sizes and traffic congestion that will affect order delivery. Indeed, increasing activities in urban fulfilment could result in worse traffic congestion, which will affect city life.

So, what is the best urban fulfilment strategy to deliver a high customer shopping experience?

How can retailers work together with city officials to create as minimal disruptions to city life as possible?

These are but some of the questions that retailers and policymakers alike need to grapple with within the next decade.

<sup>1</sup> Urban fulfilment centers: Helping to deliver on the expectation of same-day delivery. Deloitte, 2019.



### Debjit Roy

**Associate Professor of Operations Management**

Indian Institute of Management Ahmedabad, India

Tel: +91 796 632 4823

[debjit@iima.ac.in](mailto:debjit@iima.ac.in)

<https://faculty.iima.ac.in/~debjit/>

### Stefanus Jasin

**Associate Professor of Technology and Operations**

Stephen M. Ross School of Business, University of Michigan, Ann Arbor, U.S.

Tel: +91 734 764 2305

[sjasin@umich.edu](mailto:sjasin@umich.edu)

[www.sites.google.com/a/umich.edu/sjasin1](http://www.sites.google.com/a/umich.edu/sjasin1)

### Joline Uichanco

**Associate Professor of Technology and Operations**

Stephen M. Ross School of Business, University of Michigan, Ann Arbor, U.S.

Tel: +91 617 999 7258

[sjasin@umich.edu](mailto:sjasin@umich.edu)

[www.sites.google.com/a/umich.edu/juichanco](http://www.sites.google.com/a/umich.edu/juichanco)

# Physics: Building for discovery in the global context

Jim Siegrist, Associate Director for High Energy Physics at the Office of Science, U.S. Department of Energy details how the organisation is building for discovery, using the excellent example of their High Energy Physics program

**T**he pursuit of science drives innovation. Big questions attract bright minds and these dedicated scientists and engineers solve big problems. Discovering the nature of our universe, for instance, demands experiments that operate in the extremes, from ultra-sensitive deep underground detectors to space-based experiments and the largest machine ever constructed, the Large Hadron Collider.

Delivering scientific discoveries that advance human knowledge requires pushing the frontiers of technology. The new tools that are developed, in turn, impact energy, the economy and national security. This engine of innovation is the core mission of the U.S. Department of Energy's (DOE) Office of Science. As the largest federal sponsor of basic research in the physical sciences in the United States, the DOE Office of Science supports scientists and engineers at hundreds of institutions across the country and stewards ten national laboratories that host tens of thousands of users each year across their facilities.

DOE user facilities provide some of the most advanced tools of modern science, including the world's fastest supercomputer, facilities for studying the nanoworld, the environment and the atmosphere, as well as world-class light sources, neutron sources, particle accelerators and colliders. These facilities are available to all users, without regard to nationality or institution, based on the scientific merit of the proposed work. Use of the facilities is also free for research intended to be published in the open literature. This strategy aims to enable scientists to use the best possible resources in their pursuit of discovery. To keep advancing our science program, the Office of Science is continually investing in this infrastructure and building for discovery.

For example, the High Energy Physics program, which seeks to understand how the universe works at its most fundamental level, is bringing together scientists from around the globe to create a U.S.-hosted world-class facility to study the science of neutrinos. There are three known types of neutrino but these ghostly neutral particles, a million times lighter than an electron, change their type as they travel from one point to another. The first clue to this puzzling behaviour was observed fifty years ago by Ray Davis, Jr., whose Nobel Prize-winning work found fewer neutrinos than expected from the sun in a detector in the Homestake Mine, a mile underground in the Black Hills of South Dakota.

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**“The DOE Office of Science invests in the future. The technology our scientists and engineers develop not only enables advances in science but impacts medicine, industry and national security. Our user facilities provide advanced tools that enable scientific discovery. We work with partners around the globe to create truly world-leading instruments to tackle some of the biggest questions in science.”**

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Now we are returning to the same mine to host the international Deep Underground Neutrino Experiment, which will precisely measure this oscillation of neutrino types while aiming to measure any difference between the matter and antimatter versions of neutrinos. Over a thousand scientists from around the world are collaborating to build this experiment and their work may help us understand why the universe today is made of matter instead of antimatter. Eight hundred miles away, the Long-Baseline Neutrino Facility under construction at Fermi National Accelerator Laboratory will support this experiment by sending the world's



most intense neutrino beam directly through the earth between Illinois and South Dakota. We're also working with international partners on a new linear accelerator that will power the Fermilab Accelerator Complex, serving this and future world-leading experiments.

Our scientists and engineers also apply their expertise to international experiments and facilities hosted elsewhere. Our long and successful partnership with CERN began with agreements signed in 1997, enabling U.S. scientists to provide important accelerator and particle detector components to the Large Hadron Collider programme. The Large Hadron Collider provides the only way for particle physicists to create and study the Higgs boson, which was discovered in 2012 and led to the 2013 Nobel Prize in Physics for its role in revealing the origin of mass of subatomic particles. The new bilateral U.S.-CERN agreement signed in 2015 enables over a thousand U.S. scientists to continue their collaborative research at the world's highest energy particle collider, while developing and building accelerator and detector components for the future High-Luminosity Large Hadron Collider programme.

In Chile, the construction of the Large Synoptic Survey Telescope is underway in order to perform a ten-year optical imaging sky survey of nearly forty billion stars and galaxies in the southern hemisphere. The unprecedented amount of data it will provide will enable scientists to probe the nature of dark energy, which is accelerating the expansion of the universe. The National Science Foundation (NSF) leads LSST and the DOE Office of Science is contributing the largest digital camera ever constructed, with over three billion pixels, to record high-quality images with minimal downtime. In parallel, DOE is building the Dark Energy Spectroscopic Instrument, which DOE will operate on NSF's Mayall Telescope in Arizona. It will provide complementary optical spectra of tens of millions of galaxies, enabling scientists to build a three-dimensional map of the nearby universe to shed light on dark energy. LSST and DESI will make their data publicly available after a proprietary period.

A suite of experiments are exploring the nature of dark matter, which accounts for five times as much of the universe as all ordinary matter combined. Dark matter could be created and detected using beams of particles from accelerators, such as the Large Hadron Collider or a number of DOE national laboratory facilities. Ultra-sensitive detectors deep underground are searching for signs of galactic dark matter as it passes through the earth. Our investments in technology development are also creating new types of detectors based on quantum sensors, which may find an early application in searches for ultralight dark matter particles that were previously thought inaccessible to experiment.

The DOE Office of Science invests in the future. The technology our scientists and engineers develop not only enables advances in science but impacts medicine, industry and national security. Our user facilities provide advanced tools that enable scientific discovery. We work with partners around the globe to create truly world-leading instruments to tackle some of the biggest questions in science. By providing enticing scientific challenges and offering world-class facilities that can help meet those challenges, the U.S. Department of Energy attracts the next generation of innovators to our programs and trains them to be the leaders of tomorrow. ■

### **Jim Siegrist**

#### **Associate Director for High Energy Physics**

Office of Science, U.S. Department of Energy

[news@science.doe.gov](mailto:news@science.doe.gov)

[www.energy.gov/science/office-science](http://www.energy.gov/science/office-science)

[www.twitter.com/doescience](https://www.twitter.com/doescience)

# Physics: Negative ion formation in complex heavy systems

Dr Alfred Msezane from Clark Atlanta University's Department of Physics lavishes us with his knowledge about an intriguing aspect of physics, which focusses on his research on negative ion formation in complex heavy systems

The investigation of negative ion formation in low-energy electron elastic collisions with complex heavy systems through the total cross sections (TCSs) calculation provides a novel and robust approach to producing unambiguous and definitive relevant atomic and molecular data for the first time. The novelty and generality of the Regge-pole approach is in the extraction of the anionic binding energies (BEs) from the calculated TCSs for the complex heavy systems; for ground state collisions these BEs yield the definitive theoretically challenging to calculate electron affinities (EAs). Much has been reported and discussed in the published literature about negative ions in general from various perspectives, including their nature and applications. The major objective here is the production of reliable data for complex heavy systems, such as the lanthanide and actinide atoms and fullerene molecules through low-energy electron elastic scattering TCSs calculations. This presentation toward quality data production is organised for convenience in the following four inter-connected subtopics: I. Overview and novel robust theoretical approach; II. Ground state negative ion formation in complex heavy systems: electron affinity extraction; III. Metastable and excited states negative ion formation in fullerene molecules: new insights; and IV. Negative ion formation in the lanthanide and actinide atoms: determination of reliable EAs.

## I.1 Overview

One of the most challenging and lingering problems in atomic and molecular physics and still continues to plague both experiments and theory alike when exploring negative ion formation in complex heavy atoms and fullerene molecules is the determination of the unambiguous and reliable electron affinities (EAs) of the atoms and molecules involved. Indeed, the published literature abounds in ambiguous and unreliable EAs for the lanthanide and actinide atoms. Also calculating the EAs of complex heavy systems is a formidable task for conventional theoretical methods due to the presence of the large and diverse intricate electron configurations. The use of theoretical methods that account correctly for the important physics, viz. electron-electron correlation effects and core-polarization interaction is fundamental to the reliable investigation and understanding of negative ion formation in complex heavy systems. This is the adopted approach in the investigation here.

Essentially, many existing experimental measurements and sophisticated theoretical calculations have considered the anionic BEs of the electron attachment to metastable and/or excited anionic states leading to stable negative ion formation to correspond to the EAs of the considered complex heavy atoms, such as the lanthanide and actinide atoms.

Indeed, this is contrary to the usual meaning of the EAs found in the standard measurement of the EAs of such complex systems as atomic Au and Pt as well as of the fullerene molecules from  $C_{20}$  through  $C_{92}$ . In these systems, the EAs correspond to the anionic binding energies for electron attachment to the ground state of the formed negative ions. Therefore, there must be a consistent and definitive meaning of the EA to avoid the proliferation of ambiguous and confusing meaning of the EAs of these complex heavy systems.

Unfortunately, progress toward a theoretical understanding of the fundamental mechanism underlying low-energy electron scattering from complex heavy atoms, including fullerene molecules, leading to stable negative ion formation has been very slow. In the lanthanide and actinide atoms, the presence of many intricate and diverse electron configurations that characterise low-energy electron interactions in these systems leads to computational complexity. This renders very difficult to obtain unambiguous and reliable electron affinities (EAs) for complex heavy systems using conventional theoretical methods consisting of large notoriously slow converging expansions. In particular, electron affinities calculated using structure-based theoretical methods tend to be riddled with uncertainties.

## 1.2 Novel and robust theoretical method

In recent years, the Regge-pole methodology has proved to be essential to the determination of reliable negative ion formation in low-energy electron collisions with complex heavy systems through the TCSs calculation. Regge-poles, singularities of the  $S$ -matrix, are generalised bound states within the complex angular momentum (CAM) description of scattering; they are, therefore, appropriate for the present investigations. The great advantage of the Regge-pole calculated electron elastic total cross sections (TCSs) is the extraction from them of the energy positions of the characteristic Ramsauer-Townsend (R-T) minima, shape resonances and the dramatically sharp resonances manifesting ground, metastable and excited states negative ion formation. The novelty and generality of the Regge-pole approach used here is in the extraction of the binding energies (BEs) of the anionic ground states from the calculated elastic TCSs of the complex heavy systems; these BEs have been identified with the measured EAs.

Within the CAM theory, the calculation of the TCS embeds fully the essential electron-electron correlation effects. Its calculation uses the Avdonina-Belov-Felfli (ABF) potential which accounts for the vital core-polarization interaction. The ABF potential has the appropriate asymptotic behaviour and accounts properly at low electron impact energy for the polarization interaction (both ground and excited states). It has five turning points and four poles connected by four cuts in the complex plane. The presence of powers of the charge  $Z$  as coefficients of the  $r$  and  $r^2$  ( $r$  is the radial distance) in the ABF potential ensures that spherical and non-spherical atoms and fullerenes are correctly treated. Also appropriately treated are small and large systems.

## 1.3 Accomplishments

The EAs provide a stringent test of the theoretical methods when the calculated EAs are compared with those from reliable measurements. Accurate and reliable atomic and molecular EAs are essential for understanding chemical reactions, whose importance and vast utility in terrestrial and stellar atmospheres as well as in device fabrication, catalysis, organic solar cells and drug delivery are well-documented.

Unfortunately, the published literature abounds in ambiguous and difficult to interpret EA values for complex heavy systems, particularly for the experimentally difficult to handle radioactive actinide atoms. Entirely new in the field of electron-cluster/fullerene collisions, the Regge-pole method has been benchmarked on the measured EAs of atomic Au and Pt as well as of  $C_{60}$  and  $C_{70}$  fullerene molecules yielding an outstanding agreement. The method requires no assistance whatsoever from either experiment or other theory to accomplish the remarkable feat. Indeed, very recently, it has been demonstrated for the first time that the ground state anionic BEs extracted from our Regge-pole calculated elastic scattering TCSs for  $C_{20}$  through  $C_{92}$  fullerenes matched excellently the measured EAs for these fullerene molecules. This is an unprecedented theoretical achievement; existing theoretical calculations are still struggling to go beyond the  $C_{60}$  fullerene because the EAs are at the heart of the fullerene shell model potentials.

In our research, the characteristic R-T minima, shape resonances and the ground, metastable and excited anionic BEs are extracted from the calculated TCSs for complex heavy systems, focusing mainly on the ground state anionic BEs. In the process, the following have been exposed and elucidated: 1) Novel mechanism for creating long-lived

metastable atomic negative ions by exploiting the orbital collapse mechanism in the lanthanide and actinide atoms, impacting significantly the polarization interaction; 2) Manifestation of polarization-induced fullerene-like behaviour in the TCSs for the large actinide atoms Pu and Lr due to the size effects; 3) Multiple functionalisation of large fullerene molecules through the rich negative ion resonances in their TCSs; and 4) Effective use of Regge Trajectories to probe electron attachment at the fundamental level in multi-electron systems. They are also used to delineate and identify ground, metastable and excited states negative ion formation through the anionic BEs. And importantly, these Trajectories are essential in assessing the role of relativity in the TCSs calculation.

Recently, the conundrum in the measured EAs of the complex heavy atoms Eu, Tb, Tm, Nd and Nb has been clarified and resolved through the scrutiny of the calculated electron scattering TCSs using our robust Regge pole methodology. It has been concluded that the measured and previously calculated EAs for the investigated atoms, including the most recent measurements of the EAs of Eu and Nb correspond to the BEs of excited anions of these atoms. This demonstrates the importance of our research.



### Dr Alfred Msezane

Department of Physics,  
Clark Atlanta University  
Tel: +1 404 880 8663  
amsezane@cau.edu  
[www.cau.edu/departments-of-physics/](http://www.cau.edu/departments-of-physics/)



# Ireland: A world leader in research and innovation

John Halligan TD, Minister of State for Training, Skills, Innovation, Research and Development charts the research and innovation landscape in Ireland today

Over the past thirty years, Ireland has built a growing reputation for scientific excellence and is a world leader in generating and using new knowledge for economic and social progress. Innovation is a cornerstone of Ireland's overall economic development policy. As a small country, we know that innovation is key to maintaining competitiveness for Ireland in global markets - and thereby providing employment and sustainable growth in our economy. We recognise that innovation is crucial to creating and maintaining high-value jobs and attracting, developing and nurturing business, scientists, researchers and innovators.

Ireland is one of the leading RDI (Research, Development and Innovation) locations in the world. It offers the ideal commercial, political and social environment for companies to carry out successful and profitable RDI activities. This has attracted global leaders in key high-tech industries to undertake RDI projects in areas such as pharmaceuticals, biotechnology, medical devices, ICT and financial services.

Innovation 2020 is our cross-government strategy for research and innovation, science and technology. Launched in 2015, it contains a large number of initiatives to support broad-based innovation, focusing on excellence, talent and impact to deliver on our vision to become a global innovation leader, driving a strong, sustainable economy and a better society.

From pre-primary through to further and higher education and throughout an individual's career, skills and knowledge need to be continuously enhanced if individuals, employers and countries are to realise their potential. Our success has always depended and will always depend, on our people.

To address the many global challenges that we face across society and the economy, we are ensuring that future generations of problem solvers can be inspired. Science Foundation Ireland (SFI) is the national foundation for investment in scientific and engineering research. Its work in promoting science, technology, engineering and mathematics (STEM) to the public stimulates very important public conversations around scientific research and encourages young people to consider pursuing a career path in these areas.

Initiatives being funded through SFI's Discover programme help generate enthusiasm for STEM and highlight the individual, societal and economic value of encouraging more people in Ireland to get involved.

It is vital that Ireland has a strong pipeline of STEM talent and cohorts of academically outstanding future research leaders with the skills and knowledge required to address the future challenges of an ever-changing work environment. Enhancing skills, developing and attracting talent is a pillar of the Irish Government's Future Jobs Ireland plan.

Further to this, earlier this year I launched the SFI Centres for Research Training, aimed at providing 700 PhD students trained in digital, data and ICT skills for the future, in collaboration with industry. Ireland will take a cohort-based approach to research training, allowing for better integration and collaboration across disciplines and ultimately, individuals who are well-rounded, well-equipped and confident to help achieve our RDI ambitions. The cohort approach will expose students to the wider scientific relevance of their research, encourage peer-to-peer learning and facilitate the establishment of networks, empowering them to take on positions of leadership.

Supporting collaboration between academics and industry is something that we have been very successful here in Ireland. It is an important part of how we transfer knowledge from our higher education institutions (HEIs) to industry.

Ireland's pro-business knowledge transfer eco-system is proven. Our business development agency, Enterprise Ireland, works with researchers in higher education and other research performing organisations (RPOs) to help maximise the commercial return from publicly-funded research. Investment in RPOs the length and breadth of the country is critical and as such, it must go hand in hand with an effective strategy to put that research into the hands of businesses for the benefit of the Irish economy and society. The commercialisation of public research to drive innovation and Ireland's economic competitiveness is a key pillar of Innovation 2020. Our recently revised National IP Protocol is a key element of that strategy. The revised IP Protocol is the product of an extensive consultative process facilitated by Knowledge Transfer Ireland with representatives from industry, investors, entrepreneurs, agencies and research organisations to ensure that government policy supports all types of enterprises engaging with publicly-funded research in Ireland.

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**“Innovation 2020 is our cross-government strategy for research and innovation, science and technology. Launched in 2015, it contains a large number of initiatives to support broad-based innovation, focusing on excellence, talent and impact to deliver on our vision to become a global innovation leader, driving a strong, sustainable economy and a better society.”**

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Generating and using new knowledge for economic and social progress is a key priority. By transforming the level and quality of interactions between our higher education research institutions and enterprise, we are developing a strong capacity to commercialise our public research and we are ranked first in the world for knowledge diffusion.

International cooperation maximises the impact of international and national investment in research and innovation. It contributes to the development of Ireland as a research and enterprise partner, underscoring and enhancing the excellence of our research and innovation system and facilitating engagement



**John Halligan TD**

with the Irish diaspora. A significant component of our engagement in international cooperation is the participation by our researchers and enterprises in the EU Framework Programme for Research and Innovation. The benefits of Horizon 2020 extend far beyond the potential monetary rewards. It provides a mechanism to network and collaborate with the best researchers and leading companies across Europe and engages the RDI community in addressing common societal challenges. These benefits are particularly important for a small, island nation.

In the current context, more than ever, it is vital that we harness the considerable abilities of Ireland's researchers, to give our businesses the best possible competitive edge on the global stage. ■

**John Halligan TD**  
**Minister of State for Training, Skills, Innovation,**  
**Research and Development**

Department of Business, Enterprise and Innovation

Tel: +353 1 631 2121

[info@dbei.gov.ie](mailto:info@dbei.gov.ie)

<https://dbei.gov.ie/en/>

[www.twitter.com/EnterInnov](https://twitter.com/EnterInnov)

# SSPC investing in future innovation for the pharmaceutical sector

SSPC, the Science Foundation Ireland Research Centre for Pharmaceuticals, explains how they are recognised internationally as a hub of process innovation and advanced manufacturing for the pharmaceutical sector

New investment for SSPC, the SFI (Science Foundation Ireland) Research Centre for Pharmaceuticals was announced in early June 2019. Now recognised internationally as a hub of process innovation and advanced manufacturing for the pharmaceutical sector, the new research programme will present itself in five research themes, molecules, materials, medicines, manufacturing and modelling. Led by the University of Limerick and headquartered at the Bernal Institute, the centre will work in partnership with [University College Cork](#), [National University of Galway](#), [Trinity College Dublin](#), [Dublin City University](#), [University College Dublin](#), [Waterford IT](#) with new partners [Maynooth University](#) and [Royal College of Surgeons Ireland](#).

Minister for Business, Enterprise and Innovation, Heather Humphreys TD and Minister of State for Training, Skills, Innovation, Research and Development, John Halligan TD, announced an investment of €230 million in six SFI Research Centres as part of Project Ireland 2040. SSPC, the SFI Research Centre for Pharmaceuticals, one of those centres, will now move into their third phase of funding from 2019-2025, with much focus on advanced pharmaceutical manufacturing and novel pharmaceutical materials.

SSPC comprises a critical mass of accomplished researchers and an



*Fergal Donnelly of the European Commission gave a perspective on the state of Pharma (plus) industry at a recent SSPC event to mark a new phase of funding from 2019-2025, pictured with Denise Croker, SSPC Executive Director and Gavin Walker, SSPC Co-Director and Bernal Chair of Pharmaceutical Powder Engineering, University of Limerick*

infrastructure that is second-to-none from a global perspective. SSPC will fund 68 investigators who will collectively support over 100 PhD students and over 80 PDRA years. To mark the new phase of the centre, SSPC presented a two-day showcase called Six Years In The Making: Looking Back & Moving Forward marking SSPC's achievements, with invited guest speaker Fergal Donnelly of the European Commission (pictured), comments from alumni and the experiences of industry members.

SSPC, now recognised internationally as a hub of process innovation and advanced manufacturing for the pharmaceutical sector, has demonstrated capabilities in the design and implementation of flow chemistry, asymmetric synthesis, fundamental and applied aspects of pharmaceutical crystallization, amorphous materials,

continuous processing, novel pharmaceutical solid forms and emerging pharmaceutical technologies.

SSPC has a proven record of accomplishment in precompetitive multi-industry partnership projects and single partner projects, working with over 20 industry partners and ensuring the research is critically informed by the needs of the pharma end users. Increasing the centre's reputation globally, SSPC has now published over 400 peer-reviewed high impact publications and industry members.

SSPC has created a consortium of industry and academic partners that has been the most inclusive and collaborative pharmaceutical/academic partnership in the world. The centre exists as a link between scientists and engineers, within academia and industry in Ireland and globally, to



address crucial research questions, that face the global pharmaceutical industry. A significant success of the SSPC is its unique collaboration with international academic institutions.

Another key achievement of SSPC to-date is the presence of graduates and trainees in development positions within top pharma companies globally. The increased reputation of Ireland as a location for pharmaceutical research and the creation of a working framework to enable multi-company partnerships in the pharma sector which is unique globally. SSPC produces PhD graduates and post-doctoral researchers with specific disciplinary expertise, coupled with a broad understanding of cognate disciplines across pharmaceutical science and manufacturing. Building on our industry placement programme, the transition rate of SSPC researchers to the industry currently stands at 70% in a global context, the highest of any research centre in Ireland.

## What's next?

The new funding phase will employ nine people directly and includes 68 academic investigators across nine partner institutions. The new advanced research programme will extend into the manufacturing and modelling space, adding expertise in advanced screening, predictive modelling and drug hybrid conjugates. The research projects will belong to five research themes (PharM<sup>5</sup>), molecules, materials, medicines, manufacturing and modelling with leading academic experts:

**Molecules I:** New methodologies for the asymmetric synthesis of existing APIs and future drug candidates.

**Molecules II:** Develop molecules and methods for automated and in flow generation of targeted drug hybrids.

**Molecules III:** Rapid initial toxicity and biological efficacy testing: new chemical entities, combinations and formulations.

**Materials:** Advance our understanding of SCCMs and MCCMs in order to enable improved orally delivered drug products.

**Medicines:** Optimise the development, production and use of safe and effective medicines.

**Manufacturing:** Enabling a disruptive change in the manufacture of drug substances and drug products.

**Modelling:** New techniques to design and predict behaviour in silico in order to reduce trial-and-error experimentation.

Under the new funding model, SSPC will secure 66% of our funding from other sources, so that only 34% of funding over the next six years will now come from SFI. To achieve this, SSPC will offer an improved membership option for industrial partners, expanded co-funding mechanisms and ambitious target for participation and co-ordination of EU funding schemes. The centre welcomes targeted projects with both members and non-members offering two options, 100% industry funded proprietary projects or co-funded projects.

Fully funded projects provide organisations with the opportunity to initiate strategically important and commercially impactful research projects while retaining all the intellectual property (IP). Co-funded projects offer organisations the opportunity to receive 50% project funding by SSPC. In this case, the IP, which can be licenced, resides with the academic institute. The IP framework in Ireland is reinforced by the European Union

(EU) rules and regulations in line with National IP Protocol. IP management is a critical component of the industry engagement model and specialised business incubation facilities are accommodated on each partner campus.

SSPC is currently recruiting 38 PhD students and 15 post-doctoral researchers, to be in place by October 2019, a further cohort will be recruited early 2020 across Ireland.

Interdependencies and synergies within the broader research programme will form a solid basis for multi-disciplinary targeted research projects with industrial partners. Under the Directorship of Professor Michael Zaworotko and Professor Gavin Walker, SSPC has the capacity to adapt to changes in the sector and further foster innovation and discovery.

[www.sspc.ie](http://www.sspc.ie) #wearesspc



**Louise O'Neill**  
**Marketing & Communications Manager**  
 SSPC, the SFI Research Centre  
 for Pharmaceuticals  
 Tel: +353 61 234 675  
[louise.oneill@sspc.ie](mailto:louise.oneill@sspc.ie)  
[www.sspc.ie](http://www.sspc.ie)  
[www.twitter.com/SSPCentre](https://twitter.com/SSPCentre)

# Looking ahead: Negotiating and managing the European Union budget

Here, Editor of Open Access Government, Jonathan Miles, investigates the responsibilities of Günther Oettinger, the European Commissioner for Budget & Human Resources in managing the European Union budget, including how it will benefit research

Günther Oettinger is the European Commissioner for Budget & Human Resources and his responsibilities include negotiating and managing the European Union budget and ensuring it is invested in the best manner possible to serve the people of the European Union (EU).<sup>1</sup>

## The EU's next long-term budget 2021-2027

In this vein, the most recent development here concerns the European Commission's call for leaders push towards advancing the negotiations on the EU's next long-term budget 2021-2027. This will enable an agreement to be reached by autumn 2019. The European Commission notes that time is running out and hold-up to the next EU budget is costly. Certainly, not having an agreement in time would affect researchers and farmers, students, farmers and researchers, as well as everybody else who benefits from the EU budget.

The Commission also notes that the EU's current long-term budget 2014-2020 was adopted six months too late and as such, had negative consequences for many EU citizens, in the Member States and beyond. European Commissioner in charge of Budget and Human Resources, Günther H. Oettinger notes: "Thanks to the good work of three consecutive Council Presidencies, we have already reached partial agreement on 12 sectoral files, while negotiations can start on further 16. Most importantly, an agreement on the overall framework is needed. And we need to reach it as quickly as possible – in the name of our students, farmers and researchers, among many others who count on the EU budget."

Certainly, delivering the next budget without delay means concrete impacts: tens of thousands of research jobs already in 2021 and many more in the wider economy will be created; it will enable 1,000,000

young people to benefit from an Erasmus exchange; it will permit 40,000 young people to engage in solidarity action across Europe in 2021 and; it will ensure that no less 100,000 Cohesion Policy projects start on time.

Other benefits of delivering the next EU budget on time include upping defence investments and capabilities; protecting the Union's borders against trafficking, smuggling and fraud and; assisting start-ups and small and medium-sized companies to realise their investment.<sup>2</sup>

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**"The draft 2020 EU budget is the last budget proposal of the Juncker Commission. It seeks to continue supporting EU's priorities- jobs, growth, young people, climate change, security and solidarity- and to prepare the transition to the next budgetary cycle. I invite the Council and the new Parliament to come to a timely agreement that would provide stability for the EU's future."**

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## Hosting world-class supercomputers

We continue to look ahead to the EU's next long-term budget and also the European Commission's Digital Europe Programme and note that Commissioner Oettinger said there will be a great deal of investment in world-class supercomputing and data infrastructure.

In early June 2019, we discover that the eight sites for supercomputing centres have been selected across the EU. The aim of this initiative is to support Europe's researchers, businesses and industry to help them develop new applications in many areas, such as fighting climate change, as well as designing medicines and new materials.

We learn that high-performance computing capabilities are crucial for strategic autonomy and innovation in any field, not to mention generating growth and jobs. One



*Günther Oettinger, the European Commissioner for Budget & Human Resources*

benefit of them is that they are a very important part of the development of artificial intelligence (AI) and they also boost Europe's strengths in blockchain and cybersecurity.

Commissioner Oettinger comments on this new initiative, which is part of looking ahead to the EU's next long-term budget 2021-2027: "This initiative demonstrates how joint investment between the EU and its Member States in support of a common objective can contribute to making Europe a leader in a high-technology sector, bringing significant benefits to all European citizens and businesses. We are now looking ahead to the EU's next long-term budget and to our Digital Europe Programme, through which we have proposed a significant amount of investment in deploying a world-class supercomputing and data infrastructure."<sup>3</sup>

## **EU budget 2020**

Finally, let's briefly look at the last budget that falls under the current 2014-2020 long-term EU budget, which aims to optimise funding for existing programmes and new initiatives and boost European added value in line with the priorities of the Juncker Commission. Concerning this, Commissioner Oettinger comments: "The draft 2020 EU budget is the last budget proposal of the Juncker Commission. It seeks to continue supporting EU's priorities- jobs, growth, young people, climate change, security and solidarity- and to prepare the transition to the next budgetary cycle. I invite the Council

and the new Parliament to come to a timely agreement that would provide stability for the EU's future."

In closing, the 2020 EU budget will support €13.2 billion for research and innovation across Europe under the Horizon 2020, which is just a part of the €83 billion plus in commitments to boost economic growth and European regions. Certainly, the largest and final tranche of the EU research and innovation programme (+6.4% compared to 2019) – including the final pilot phase of the European Innovation Council to support top-class innovators, small companies and scientists and give them the potential to scale up rapidly in Europe and beyond.<sup>4</sup> ■

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### **Jonathan Miles**

#### **Editor**

Open Access Government

[editorial@openaccessgovernment.org](mailto:editorial@openaccessgovernment.org)

[www.openaccessgovernment.org](http://www.openaccessgovernment.org)

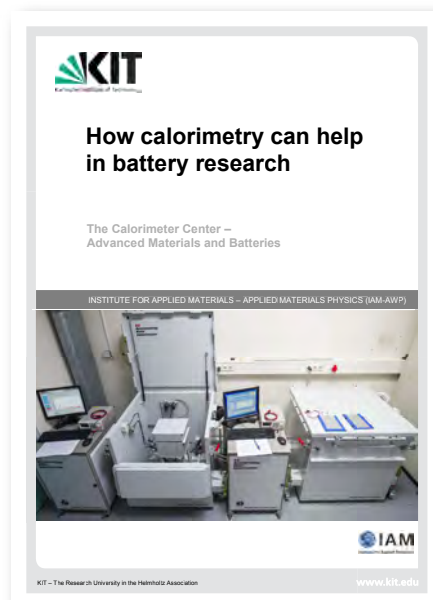
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# How calorimetry can help in battery research

Established in 2011 the Calorimeter Center at the Karlsruhe Institute of Technology's (KIT) Institute for Applied Materials - Applied Materials Physics, operates Europe's largest battery calorimeter laboratory. It provides six Accelerating Rate Calorimeters (ARCs) of different sizes, from coin to large pouch or prismatic automotive format, which allow the evaluation of thermodynamic, thermal and safety data for Lithium-ion cells on material, cell and pack level under quasiadiabatic isoperibolic and environments for both normal and abuse conditions electrical, (thermal, mechanical).



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# Carbon nanotubes: A material on the horizon

The Flavel research group at the Institute of Nanotechnology in Karlsruhe are investigating new ways to prepare type selected carbon nanotubes with industrially relevant processes on the large scale, as this profile uncovers

Carbon nanotubes (CNTs) are an allotrope of carbon having the form of a hollow cylinder and are often compared to rolled-up sheets of graphene. The cylinder wall is composed of a layer of carbons atoms and depending on the number of concentric layers they are classified as single-walled (SWCNTs) or multi-walled (MWCNTs), but the term double-walled carbon nanotubes (DWCNTs) is also often used in the case of two walls. A single carbon cylinder, be it a SWCNT or a component wall of a MWCNT has a certain 'twist' or chiral angle, which is mathematically captured by the two indices 'n' and 'm'. The n,m indices not only completely describe nanotube chirality, but they also determine the closely related nanotube diameter and the electronic band structure. Thus, it is the chirality of the CNT that has the most impact on its optical and electronic properties. A slight change of the chiral angle yields nanotubes that are metallic conductors or low or high band gap semiconductors. For semiconducting CNTs, the band gap is inversely proportional to the diameter.

The ability of chirality to tailor their material property has resulted in CNTs being one of the most intensively studied nanomaterials of the past two decades and our fundamental understanding of their unique electronic, physical, chemical and optical properties has grown enormously.

Coinciding with these discoveries is the growth of an ever-increasing list of potential applications for CNTs and these can be found across all fields of science from photonics, telecommunications, batteries, fuel cells, high frequency transistors, biosensors, novel memory devices, cancer research and solar cells.

CNTs meet all of the requirements for next-generation electronics to become environmentally stable towards humid, hot or high ultraviolet radiation conditions, become flexible and potentially be made entirely from carbon to aid disposal at the end of the product life-cycle. For example, metallic SWCNTs (m-SWCNTs) have been shown to exhibit current densities on the order of  $10^8 \text{ A cm}^{-2}$  and semiconducting SWCNTs (s-SWCNTs) to have field effect mobilities of  $10^5 \text{ cm}^2 \text{ V}^{-1} \text{ s}^{-1}$ . Likewise, the chirality dependent absorption and fluorescence spectra of CNTs are a key driver for their use as on-chip nanoscale light emitters, biomarkers or light sensitive elements in solar cells. Spectroscopy of SWCNTs reveals sets of chirality dependent absorption bands in the infrared, visible and ultra-violet wavelength regimes.

Despite their amazing properties, two decades of research and the promise of future applications, the reality is that the number of real-world uses for CNTs remains limited. Single chirality CNTs have remained an exotic nano-

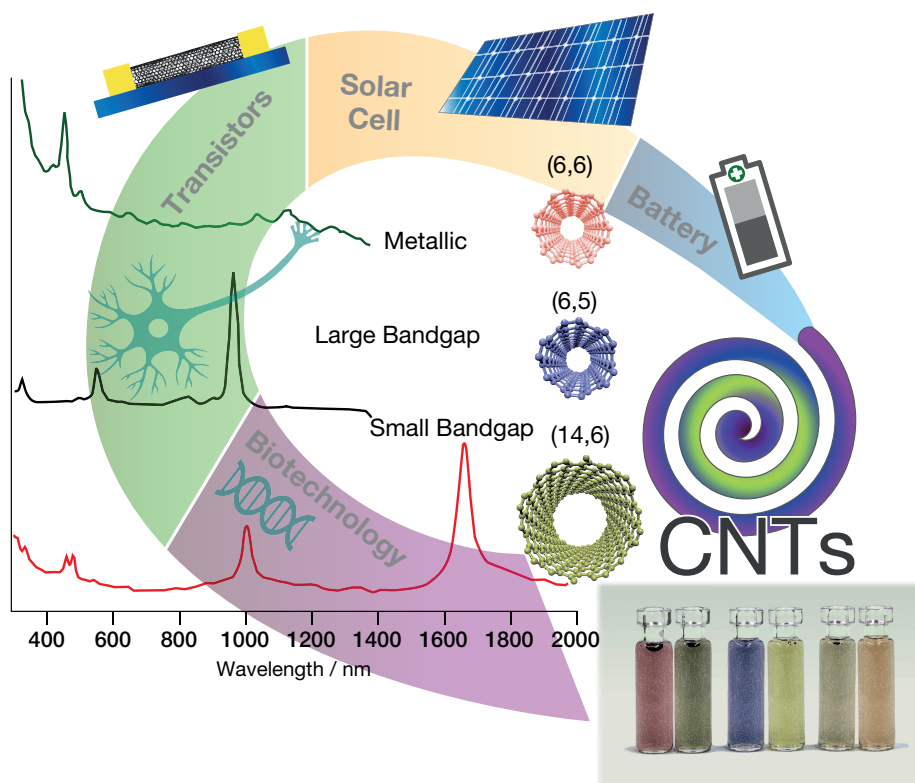


*Dr habil. Benjamin S. Flavel*

material that is only available in the research laboratory from which proof of principle devices can be made but these rarely reach the market. This is because type selected CNTs currently do not fulfil the most basic of engineering requirements; chirally pure CNTs are not available in large quantities, require costly chemicals to synthesise, suffer poor reproducibility between batches and these are time intensive to prepare. These problems are related to their synthesis. To date, there is still no method to selectively grow CNTs with arbitrary control over the (n,m) type and most synthesis methods produce a 2:1 mixture of over thirty different semiconducting and metallic chiral species.

Post-synthesis sorting and processing are, therefore, necessary and the





efficacy at which the 2:1 as-grown mixture of CNTs can be dispersed, enriched and separated according to their diameter, length, wall-number, electronic property, chirality and even enantiomeric type has come a long way. Highly selective separation techniques have been developed in both aqueous and organic solvents and it is precisely these techniques which have enabled many of the aforementioned proof of principle devices. However, the finesse of aqueous based techniques far surpasses that of organic extraction and affords not only a much larger library of single chirality CNTs but also provides industrially relevant quantities.

These techniques are reliant upon the use of surfactants which form (n,m) specific surfactant shells around the CNTs when dispersed in water. It is these differences in the surfactant shell which modulate the interaction of the CNTs with a third medium (size exclusion gels, density gradient mediums, polymers, or DNA strands) and

what the team in Karlsruhe use for separation. To date, the team have developed automated gel-based methods to prepare milligram quantities of metallic and semiconducting carbon nanotubes, chirality pure single-walled carbon nanotubes and even double-walled carbon nanotubes sorted by their inner- and outer-wall electronic type.

However, most recently the team developed an approach to separate CNTs in one to three steps using an aqueous two-phase (ATPE) system consisting of polyethylene glycol (PEG) and dextran (DX). Titration experiments revealed the separation to be driven by the pH of the suspension and each (n,m) species was found to move from the bottom (DX) to the top (PEG) phase at a unique pH. This results in a methodology that is as simple as pipetting known volumes of acid, stirring and allowing the desired nanotube to separate. It is also compatible with existing industrial processes and can easily be scaled-up.

This is a very exciting time for CNTs because we can now start to talk about real-world applications, explains Dr Flavel and the team are currently concerned with controlling the order and orientation of CNTs on the macro scale. To this end, they are preparing CNT-inks with liquid crystal concentrations from which highly aligned nanotube thin films over large areas are possible. Already, this newfound control is allowing the team to use CNT thin films as the electrode material in silicon: nanotube solar cells with an impressive power conversion efficiency of 16% or with the goal of creating an all-carbon solar cell as the light harvesting layer in combination with fullerenes.

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**Dr habil. Benjamin S. Flavel**  
 Institute of Nanotechnology,  
 Karlsruhe Institute of Technology  
 Hermann-von-Helmholtz-Platz 1, 76344  
 Eggenstein-Leopoldshafen  
 Germany  
 Tel: +49 (0)721 6082 6977  
 benjamin.flavel@kit.edu  
 http://www.int.kit.edu/flavel

# Science and higher education for the future of Portugal

Here, we speak to Manuel Heitor, Portuguese Minister of Science, about how science and higher education in Portugal are helping to turn the country into a knowledge hub for future generations, amongst other things

**M**anuel Heitor is the Minister of Science, Technology and Higher Education for Portugal. He was formerly the Secretary of State for Science, Technology and Higher Education from 2005 to 2011. He founded the Lisbon Centre for Innovation, Technology and Policy Research in 1998. He is also a Research Fellow of Texas University and co-founder of the international network Globelics.

In this interview, he discusses plans for the future of Portugal, highlighting the necessity of a relationship between the public sector and research institutions, touching on his strategy for improving employment and taking us behind the scenes on Portugal's leap into the stars, with their new Space Agency.

## **First, tell us your thoughts on how science and higher education in Portugal are helping to turn the country into a knowledge hub for future generations.**

Certainly, that is true everywhere and anywhere, it is not news, we have known that for many, many decades. Certainly, learning from the experience of the United Kingdom (UK) amongst many other places. But more and more we have realised that science creates employment, creates markets and, in particular, it creates better employment.

And this process, we know is complex. We should and we are, engaged in an overall strategy to speed up our confidence to develop our knowledge. What we did over the last years is to increase public expenditure and to stimulate business expenditure in a way that we can put together a path in the coming decades, so that we can double public expenditure by 2030 and multiply by four, our business expenditure.

The last two years have given us the belief that we can possibly do this by creating more and better employment, again, since 2015 we have been growing steadily in this area, year after year. And the key issue is how can we guarantee this, steady increase, in the overall effort, particularly by increasing business expenditure. We have improved all our landscapes of institutions through their sophistication and launched a programme to strengthen our research institutions but at the same time, to offer new institutions. Particularly, we offer deeper ties between the business sector and the public research institution by setting up a programme to establish what we call cooperative lets, to fuel the creation of better employment, through knowledge and business.

## **So ultimately, employment is one of the key benefits coming out of the work you're doing?**

Yes. And there is the belief, that we want more and more to make a reality, that science has created many markets. Through science, through knowledge-related activities, we can certainly foster better lives at large.

## **So in relation to education and science, why do you think they go well together? Why do they have such a good relationship, especially in Portugal?**

Nowadays, more and more, we cannot rely on unskilled people. Because value creation is not sustainable in a society which needs to learn and adapt, fast. And again, let's say that we are at the start of the process, particularly in relation to promoting learning capacity, of every single citizen and engaging with them. Through a process that starts early in your life, through scientific culture and through education, this process



will give people the ability to learn more and the capacity to identify opportunities to acquire knowledge. That is because a key issue again, and not just in Portugal, is that more people are asking for papers than ever before, so I believe we need to promote learning capacity more than we have done before.

**Yes, we are seeing a similar thing in the UK, where we need more people to be trained in science, technology and engineering but they are not getting the message when they are young. What are you doing in Portugal in regard to that matter?**

Essentially, we have to diversify in the way we think. There is certainly no one size fits all. But it requires a set of diversified institutional contexts, diversified learning problems, education does not have to be longer. More and more, in reality, we have short courses at the pre-university level, but also at a post-grad level and the key issue is training adults to adapt over life. Education should not be concentrated on the young generation but the process which we can give youth the capacity to learn in a fast-changing economic world. And we should require people to learn throughout all their lifetime, something that cannot be balanced with a traditional education setting. So, we need more

and more to adapt from our traditional institutions to short-timings and to diversify the supply of programmes. Certainly, combining the traditional long-term education with more and more new programmes for short-term, is something that should be done, together with the employment. It's not just a relationship of supply but also of the design of the education system which is the core responsibility of the actors involved.

**So you want to encourage a nation that is constantly learning and unafraid to go back into education when it is necessary?**

Exactly, definitely. But this requires the core responsibility to be shared with employers. And a key issue in public policy is, in fact, stimulates the sharing of that responsibility and that is the reason why we are planning to build resources and new collaborative institutions, where we stimulate with public funding a fraction of how to promote partnerships between traditional businesses and research institutions, to culture, IT, the public sector and every single area of activity. We need employers to partner with different institutions. It is particularly important to provide the correct infrastructure. This can only be done if people are engaged in research to look at the future.





**With science steadily progressing over the last 20 plus years, why is the government in Portugal keen to encourage research within the country further? As you just mentioned research is a key part of enabling education.**

Science is complex and science is social. That's the reason why we need to promote scientific culture and thought. It is easy for me as Minister of Science to say this, the key issue is, for instance, look at your sector. We know today that fighting for cancer, for example, can be done if we do more research, particularly to prevent cancer because we also know that if we do more, we can prevent more. Increasing and enhancing the beliefs of science has become part of modern society, as a responsibility of society. This is a challenging that involves everyone, it involves the need for a continuous updating on their learning category.

**I can see this is a passionate priority for you. So what would you say are the priorities of the Ministry of Science, Technology and Higher Education?**

More than priorities we have to understand that the promotion of digital skills is very, very important in any scientific or social context. Through digital media you can access so much information and, therefore, opening up access to digital skills, is easy and very critical now so we have that strategy to re-open the internet for every citizen. But beyond excess, we need to also look at participation and so the way that people participate at large. And also, in the realm of any scientific strategy, multiple things will engineer the creation of jobs. Therefore, the relation between science and employment is more and more important particularly for people at large to understand and to invest more and more in science. So, I would say excess participation



## RESEARCH AND INNOVATION

To achieve these objectives the agency will be oriented to guarantee that, by 2030, Portugal is widely recognised as a global authority in the science and economics of space-Earth-climate interactions, making particular use of “double-use” technologies for Earth Observation and including a special focus on secure and safe space-ocean interactions and methods of data science for the benefit of society.

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**“Essentially, we have to diversify in the way we think. There is certainly no one size fits all. But it requires a set of diversified institutional contexts, diversified learning problems, education does not have to be longer.”**

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Space and the development of the technologies that are associated with or derived from it are now recognised as a driver of innovation by several nations, representing an imperative for the promotion of social and economic progress and for international security. In fact, the security and well-being of our society are increasingly dependent on information and services provided from Space and it is important to point out the increasing impact of Space systems on fields such as agriculture, fisheries, infrastructure, urban development, defence and security and even the public health sector and epidemic monitoring, among others.

It should also be clear that Space should be seen as a public good, to be associated with our institutions and collective ambitions and it is critical to continue to democratise access to Space. It is in this context that Space technologies are inescapable for the future of mankind, requiring continued investment in education and culture for Space and increasingly attracting future generations of young scientists, engineers and entrepreneurs for new horizons driven by space systems. This requires strengthening initiatives to foster the scientific culture of the population at large, together with the interest of youngsters in the areas of science, technology, engineering and mathematics, as well as promoting space for education and culture. In addition, by promoting the dissemination of educational, scientific and cultural contents to populations in remote areas with difficult forms of interconnection, we all will

has relevance because ultimately, we need a better relation to scientific ones.

**I know that Portugal has recently established a National Space Agency, would you like to tell me more about that? What are your aspirations with this organisation?**

Portugal Space is an agency to be primarily considered as an instrument of the Portuguese government, in close articulation with the Regional Government of the Azores, to make Portugal a place of space-related innovation, based on scientific excellence and competitive industrial capabilities, generating high-level jobs, inspiring young generations and placing Portugal as a significant contributor of progress in the world, with a particular action on emerging forms of the “New Space”.

guarantee that space technologies can become a critical instrument through which, desirably, it is possible to enable the world for peace.

In Portugal, on the continent as well as in the archipelagos of the Azores and Madeira, it is essential to continue to support the growth of the Space sector and related applications. Twenty years after joining the European Space Agency (ESA), Portugal is now considered a success for rapid adaptation and integration into Space programs. The OECD analysis of Portugal's return on investment in Space systems shows a multiplier effect between four and five of the public funding of R & D activities. This evolution is the result of the efforts of scientific institutions and companies to develop skills and competencies in a variety of areas, including telecommunications, cyber systems, augmented reality, Earth observation, navigation systems, space exploration and launcher technology, among many other subdomains. This process of training and recognition of the Space sector that emerges in Portugal has been the target of the recent strategy of strengthening scientific diplomacy and international scientific and technological cooperation, based on five lines of action, as briefly described in the following paragraphs.

First, the "Portugal Space 2030" strategy, approved by the Government in February 2018 with the ambition of multiplying by ten the volume of activities in Portugal in the area of Space, naturally within the scope and in articulation with the "Innovation Strategy for Portugal 2018-2030, which aims to "effectively converge to Europe by 2030 and achieve R & D investment of 3% of GDP", creating about 25,000 skilled jobs in the period 2018-2030. The need to stimulate new markets, public and private partnerships in Portugal in the international context implies the development in Portugal of pilot projects of international relevance and a demonstrative context in diverse sectors, including agriculture, fisheries, monitoring of major infrastructure, urban development, defence and security.

The implementation of the "Portugal Space 2030" strategy includes three complementary instruments, as follows:

i) A new legal regime through the "Space Law" approved in 2018; ii) The creation of a space agency, "Portugal Space" ([www.ptspace.pt](http://www.ptspace.pt)), installed in March 2019; and iii) Ongoing development of a foreign direct investment attraction strategy.

In particular, the "New Space Industries" sector considers a new wave of actors and business models in the international space sector characterised by the capacity to attract private financing, in view of predominantly commercial markets and in need of communication and information systems based on mega-constellations of micro and nanosatellite. New Space opens up new opportunities for Portugal, as well as other small and medium-sized countries, namely at the level of production and use of data, based on specific technological platforms dedicated to Earth observation for social and economic activities and at generation level of data and infrastructures. It includes the need and challenge of developing and producing satellites, mainly micro and nano-satellites and the development of mega-constellations, with developments expected to democratise access to low-altitude orbits (LEO) and synchronised with the sun, that is a Sun-synchronous orbit (SSO).

Second, the development and promotion of the "Atlantic Interactions" agenda and the Atlantic International Research Center – AIR Center, in the form of an innovative network institution driven by an international R&D cooperation program to strengthen knowledge on space climate-ocean interactions through North-South/South-North cooperation. It includes the installation of an Earth observation centre on Terceira Island, in conjunction with ESA and in the form of an ESA\_Lab @ Azores.

Third, the launch of the "Azores International Satellite Launch Program – Azores ISLP" ([www.azoresislp.pt](http://www.azoresislp.pt)) and the procedures for the installation and operation of space infrastructure for the launch of mini and microsatellites in the Autonomous Region of the Azores. Its location on European Union territory in the Schengen Area, as close to Continental Europe as it is to the American continent and with extensive ocean cover over 1,500 km in any direction, offers absolutely unique advantages for the promotion and development



of “New Space” in Europe. It builds on the ongoing reinforcement of ground stations for satellite monitoring and stimulates a new challenge for Europe at large in terms of the need to consider and stimulate a new generation of launchers in terms of safety and environmental impact, as well as ensuring the unprecedented worldwide installation of a spaceport open to all international actors and operators. In other words, the installation of a new generation of environmentally sustainable and safe satellite launcher services, open to the world, can create a new positioning of Portugal and Europe at the world level.

Increasing international competition in this context has emerged rapidly, requiring a new strategy in the process of valuing the positioning of Atlantic and the real opportunities that the Azores have in this area. Portugal’s positioning of the Atlantic is, thus, critical and opens new opportunities in the international context. It facilitates, in particular, the installation of observation and measurement infrastructures in a spectrum not reachable or replicable in any other country, which represents an effective comparative advantage.

Fourth, the promotion of Portugal in the world through the reinforcement of international partnerships through the “Go Portugal – Global Science and Technology Partnerships Portugal” Program. The international prestige already achieved demands that Portugal, in the near future, positions itself as a knowledge-driven economy, with the capacity to take on the new challenges at the frontiers of the production and diffusion of knowledge. It is under this context that Space plays an absolutely fundamental role. This is, moreover, imperative for a country that seeks to affirm itself in the international scenario for science and innovation.

Activities under development include:

- The expansion of the MIT-Portugal Program and the UT Austin-Portugal Program with a specific re-orientation for space research and innovation;
- A formal agreement for a specific partnership with the Chinese Academy of Sciences, CAS, for microsatellite

development, through the installation in Portugal of “STARlab” in close cooperation with business companies operating in Portugal.

Fifthly, the promotion of the “PERIN-Portugal in Europe Research and Innovation Network”, aimed at guaranteeing an effective convergence strategy for the “Europe of Knowledge” by 2030 and facilitating the implementation of the “Innovation Strategy for Portugal 2018-2030”, through a joint and profound debate throughout the country and in priority areas for the promotion of research and development (R & D) activities, including health, artificial intelligence (AI), production and agri-food technologies.

In this context, the PERIN 2019 “+ Science, + Europe” journeys are being held between March and April 2019, under which it is Portugal’s intention is to reinforce and double its participation in the next European Research and Innovation Framework Program (i.e., “Horizon Europe”) and related programs relevant to research and innovation activities (i.e., the European Space Program and the “Europa Digital”, among others).

This is how the national agenda “Portugal Space 2030” mobilises various sectors of society for Space, as valued as a public good, fostering new opportunities for institutional, industrial and international cooperation and contributing to the development of innovative and competitive technologies in the international market. ■

**Manuel Heitor**

**Minister of Science, Technology and Higher Education**

Portuguese Republic Government

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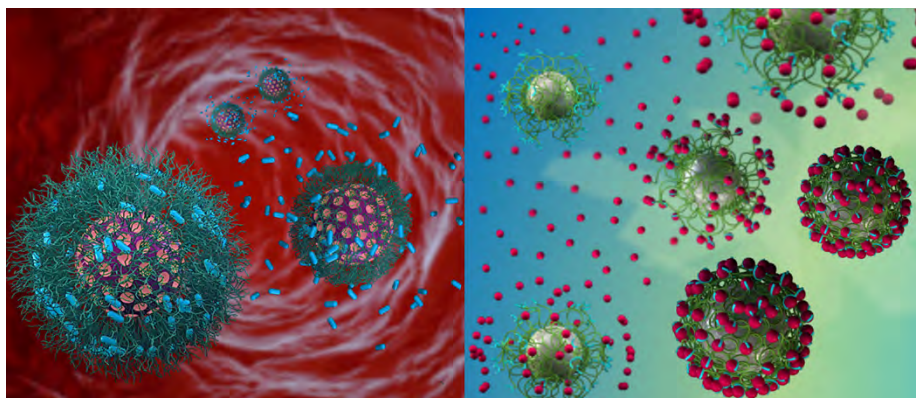
# Functional nanomaterials: Fit for purpose

Researchers at Técnico, Univ. Lisboa, share their expertise on functional nanomaterials and why they are fit for purpose

**F**unctional nanomaterials present at least one dimension in the nanometer scale, a size range that can give them unique optical, electronic or mechanical properties, which are radically different from the corresponding bulk material. Due to their small dimensions, they have very large area to volume ratio and can be further surface-engineered to provide specific functional properties that the bulk materials do not exhibit.

Initially driven by curiosity, the field of nanomaterials explored new phenomena, such as plasmonics, negative refractive index, teleportation of information between atoms and quantum confinement. With maturity came a period of application-driven research, prone to have a real societal impact and produce true economic value. Indeed, nano-engineered materials already represent a significant share of the global catalyst market and different types of nanoparticles have made their way from bench-to-bedside. Gold nanoparticles are used for on-site medical diagnostics, magnetic nanoparticles (SPIONs) provide better contrast in MRI diagnostic and drug-loaded nanoparticles are used for the treatment of ovarian and metastatic breast cancer.

In the future, we anticipate a sharp increase in the societal impact of functional nanomaterials in key areas from clean energy to environmental remediation, transportation and health.



*Figure 1. Functional nanoparticles can be tailored for specific applications in different areas from health (hybrid nanoparticles for diagnostics and tumour-targeted controlled drug delivery, left) to the environment (smart polymer nanoparticles for detection, scavenging and recovery of metals in water)*

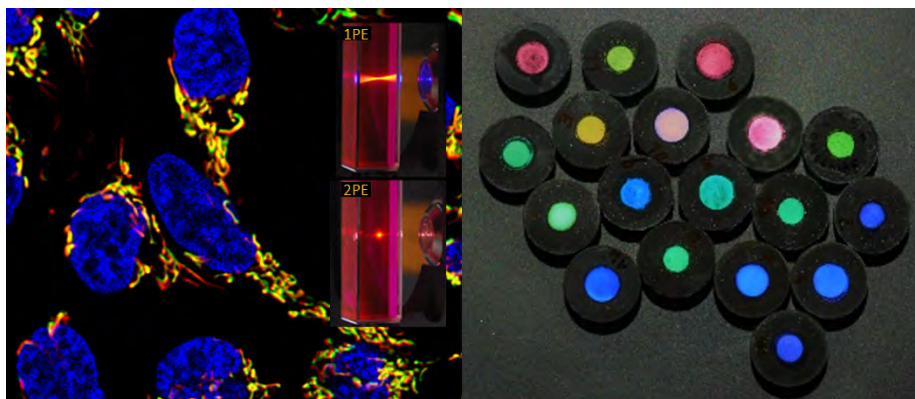
At the Optical and Multifunctional nanoMaterials (OM2) group of the University of Lisbon (Instituto Superior Técnico), we focus on exploiting the interaction of nanomaterials with light to establish clear design guidelines for developing tailored nanomaterials for applications in imaging, sensing, controlled delivery, optoelectronics and solar energy harvesting. Our work is aligned with the Sustainable Development Goals of the 2030 Agenda of the United Nations.

We aim to contribute to promoting healthy lives and well-being for all, by developing better dyes and sensors for early diagnostics and controlled drug-delivery nanoplateforms for targeted therapy. We also develop nanomaterials for environmental assessing and remediation contributing to ensure the availability and sustainable management of water and sanitation for all. Finally, our work on nanomate-

rials for optoelectronics and solar light harvesting tackles issues related to accessing affordable, reliable and carbon-free energy.

Our toolbox to design fit for purpose nanostructures includes different types of materials (hybrid nanoparticles, mesoporous materials, stimuli-responsive and fluorescent polymers, gold-dye assemblies, carbon quantum dots and optical sensor materials) and different processes (multiphoton absorption, photoluminescence and photo-induced energy or charge transfer). We combine these materials and processes to develop:

i) Brighter, specific and more stable dyes for laser-scanning fluorescence imaging based on novel fluorescent hybrid silica nanoparticles with diameters as small as 10 nm and different groups at the surface (for biological targeting, etc);



**Figure 2.** Emissive nanomaterials for efficient multiphoton emission can improve imaging quality in thick biological samples (multiphoton image of animal cells and intrinsic localisation of multiphoton excitation, vs one-photon excitation, left) and self-assembly of colourless polymer nanoparticle can provide fade-proof biomimetic structural colour (right)

ii) Nanocontainers for targeted on-demand cargo release, based on advanced hybrid nanoparticles with a core of mesoporous silica of precisely controlled diameter, different pore morphologies and tuneable surface composition (Fig. 1);

iii) Responsive surfaces and delivery-control systems based on stimuli-activated (smart) polymer nanomaterials (Fig. 1);

iv) Smart nanoparticles for metal detection, scavenging and recovery in water (Fig. 1);

v) Hybrid plasmonic nanostructures based on gold and organic/inorganic luminescent materials for brighter and more sensitive imaging and point-of-care molecular diagnostic applications;

vi) Biomimetic structural colour pigments for fade-proof inks and displays based on the self-assembling of polymer nanoparticles (Fig 2);

vii) More efficient dyes for multiphoton imaging in biological media based on push-pull organic molecules and graphene quantum dots with nonlinear emission (Fig. 2);

viii) Photoconductive materials for organic optoelectronic devices based on small acceptor molecules (perylene diimides and others) to promote efficient exciton diffusion in charge-transfer single crystal interfaces;

ix) High-density volumetric optical data storage systems based on polymers with enhanced nonlinear absorption in the near-infrared; and;

x) Solar cells and electroluminescent materials with improved efficiency based on photoactive metal-organic frameworks for tuning the charge-transfer pathways in the active media.

Light-emitting nanomaterials are key for many of our target applications. To lower the limit of detection in diagnostic applications and improve the image quality in advanced laser-scanning microscopy, we develop brighter and more photostable nanomaterials. We do so by incorporating a large number of dyes in polymer chains of controlled architecture and molecular weight or inside silica nanoparticles of precise morphology and dimensions.

Another approach is to increase the brightness of each dye by creating

nanostructures that couple the dyes to gold nanoparticles by taking advantage of the local light concentration effect of the surface plasmon. For biological applications, it is also important to have excitation and emission within the biological optical transparent window. For this purpose, we tailor the structure of dyes (e.g. perylene diimides) and nanomaterials (e.g., doped carbon dots and nanographenes) for nonlinear excitation in the favourable spectral window.

At OM2, we are committed to providing new cutting-edge solutions based in functional nanomaterials fit for applications that will help face the present and future challenges of our society in the areas of health, water and energy sustainability. Our group is committed to the challenges that our society will face in the future, providing new cutting-edge products and solutions based in functional nanomaterials.



**José Paulo Farinha**

farinha@tecnico.ulisboa.pt

**Ermelinda Mações**

ermelinda.macoas@tecnico.ulisboa.pt

**Carlos Baleizão**

carlos.baleizao@tecnico.ulisboa.pt

**José Gaspar Martinho**

jgmartinho@tecnico.ulisboa.pt

Instituto Superior Técnico,

University of Lisbon

<http://om2.tecnico.ulisboa.pt/>

[www.twitter.com/OM2\\_IST](http://www.twitter.com/OM2_IST)



# Peptides: Why advancing peptide science and technology should be a priority

Paula Gomes, Associate Professor of Chemistry and Senior Researcher in Bioorganic and Peptide Chemistry at the University of Porto, Portugal, explains why peptides are amongst the most promising molecules for the future

Research on peptides and their prospective applications has been regaining momentum, as we are running out of options to tackle life-threatening conditions, mainly due to drug safety and resistance issues. Due to their potent and selective action, a broad range of biological targets and effects and generally low toxicity and immunogenicity, bioactive peptides are currently the most appealing alternatives to the so-called “conventional drugs”, to fight neurodegenerative diseases, drug-resistant cancers and, especially, antibiotic-resistant infections in humans. Antimicrobial peptides (AMP) are being actively pursued as the antibiotics of the future, for use not only in humans but also in livestock and food plants, as there is an urgent need to find sustainable alternatives to either drugs or pesticides that are unsafe and/or no longer efficient.

The extraordinary value of peptides is not exhausted in their antimicrobial properties, as bioactive peptides are proven to be highly efficient for non-infectious diseases, as well as nutraceuticals or cosmeceuticals. For example, anti-hypertensive, antioxidant, antidiabetic, neuroactive and immuno-modulatory peptides are formed when milk is processed to produce yoghurt. Likewise, collagen-boosting peptides present in commercially available cosmetics have been under the spotlight not only for their known anti-ageing

effects but also for their wound-healing properties that could be of use in skin and soft tissue infection (SSTI) management. As life expectancy grows, active research on peptides as effective and biocompatible options to deal with hypertension, diabetes, ageing and health complications thereof, such as chronic wounds (venous/pressure/diabetic foot ulcers), is an urgent need and not merely an academic exercise.

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**“Gomes hopes that positive signs in this same direction will come up soon in more peripheral regions, as Peptide Science is crucial within strategies for smart specialisation.”**

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At the forefront of materials science and engineering, we can also find peptides, although they do not necessarily exhibit intrinsic bioactivity. In this setting, self-assembling peptides (SAP) have gained relevance for their potential use as biomimetic structures, such as collagen-like materials or components of synthetic extracellular matrices built to promote tissue regeneration. SAP have been also explored as biocompatible vehicles for intracellular delivery of drugs or bio-signaling molecules like, for example, nitric oxide, a potent vasodilator relevant in many physiological processes.

Having early perceived peptides as one of the most promising types of molecules for the future, Paula Gomes pursued her PhD in Peptide

Chemistry (1997-2000), to work on peptide-based vaccines mentored by Professor David Andreu, in Barcelona. Returning to her Alma Mater, the University of Porto, she gathered a [bioorganic & medicinal chemistry research team](#) now integrated into the [Molecular Synthesis group of the largest Chemistry-based Research Unit in Portugal, LAQV-REQUIMTE](#). Research at Gomes's lab builds on peptide chemistry principles to develop new therapeutic strategies, in close collaboration with experts from complementary areas, such as biomedical engineering, pharmaceutical sciences, biotechnology and agricultural and food sciences. The main lines of research at Gomes's lab focus on: (i) New antimicrobial and wound-healing peptides to tackle SSTI; (ii) Peptide-modified materials for diverse biomedical applications, including osteogenic growth promoters, antibacterial surfaces and nitrogen oxide releasing hydrogels; (iii) Cell-penetrating peptides as drug and nucleic acid carriers; (iv) Identification and potential applications of AMP derived from animal toxins, like snake venoms or amphibian secretions and more recently; (iv) AMP-based strategies to combat plant diseases or prevent food spoilage.

The previous are only a few of the applications that can be envisaged for peptides, explaining why interest in these biomolecules and added-value products thereof is rapidly growing in



**Figure 1:** It took 15 years for Paula Gomes to gather the necessary means to set up and consolidate a peptide synthesis lab that evolved from exclusively manual methods (top left) to fully automated synthesis using state-of-the-art multiple-channel instrumentation (right) and purification by preparative high-performance liquid chromatography (bottom left). Setting up a large-scale peptide synthesis and purification unit able to meet the requirements of industrial partners is Gomes's next goal.

diverse sectors, including the pharmaceutical industry. The latter is a relevant sign that times are finally changing, as the Big Pharma has for many years relegated peptides as prospective drugs. This has been mainly due to peptides' low oral bioavailability, extensive metabolic degradation and rapid excretion and high production costs either by biotechnological or chemical routes; however, the multiple advantages of peptides as therapeutic agents, along with latest developments in both large-scale production methods and metabolically-stable peptide analogues underpin the ongoing paradigm shift, which peptide scientists have been longing for.

The rising awareness on the scientific, technological and economic worth of peptides is starting to energise investment on peptide research and peptide production facilities. One example is the Peptide Synthesis Facility of the Faculty of Sciences of the University of Porto, which Gomes coordinates. This facility, yet unmatched in Portugal, was open to provide peptide synthesis services in 2016, thanks to Portuguese/European Union co-funding to acquire a state-of-the-art multiple synthesizer (Figure 1) the only one in

the country. According to Gomes, the next step to make Portugal truly competitive in Peptide Science, by attracting industrial partners working on or with peptides, is a large-scale production unit. Other European facilities are on this track, like, e.g., PeptLab, where a large scale peptide synthesizer has been instated on the past 12th of June. Gomes hopes that positive signs in this same direction will come up soon in more peripheral regions, as Peptide Science is crucial within strategies for smart specialisation.

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**Paula Gomes**  
Associate Professor of Chemistry  
and Senior Researcher of Bioorganic  
and Peptide Chemistry

**Secretary for the European Peptide  
Society (EPS)**

**National Representative of Portugal  
at Division VII – Chemistry and Human  
Health of the International Union for  
Pure and Applied Chemistry (IUPAC)**  
Department of Chemistry and Biochemistry,  
Faculty of Sciences, University of Porto  
Tel. +351 220 402 563  
[pgomes@fc.up.pt](mailto:pgomes@fc.up.pt)  
[www.fc.up.pt/pessoas/pgomes/people.html](http://www.fc.up.pt/pessoas/pgomes/people.html)

# Innovative nanocapsules for skin care

Here, Carla Silva, Project Coordinator, Chief Technology Officer at CeNTI – Centre for Nanotechnology and Smart Materials promotes the firm's innovative nanocapsules for skin care

Today, consumers are increasingly aware of healthy lifestyle habits and the environmental footprint of their consumer products. As such, new technologies have been developed to fulfil their needs and expectations. Among them, nanotechnology appeared in numerous industries, creating added value to daily products.

In this context, the project **SKHINCAPS** – **Skin Healthcare by Innovative NanoCAPsules** – has emerged, focused on an innovative, cost-effective, safe and sustainable *in situ* self-assembly nanoencapsulation technology, to deliver natural products for skin healthcare applications, with increased efficiency and cost benefits.

The project aims to develop textiles and cosmetics with different functionalities, depending on the nanocapsules' release mechanism.

For first layer and sports garments, in which the skin comfort is of great importance, no release nanocapsules loaded with paraffin will allow thermal management in accordance with the temperature of the environment, certainly, textiles will feel warmer at low temperatures and cooler during the summer. This effect was maintained even after several washing cycles, as confirmed by Differential Scanning Calorimetry (Fig. 1A).

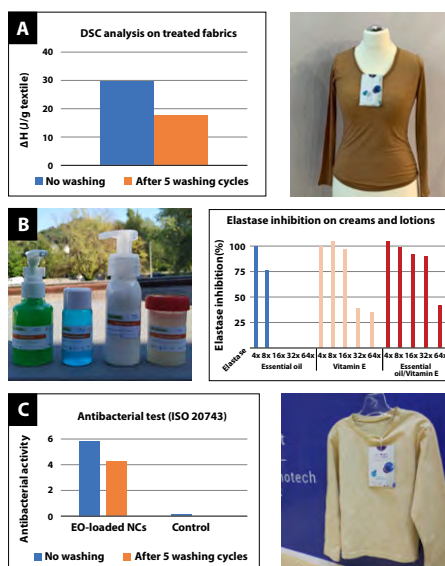


Figure 1. Performance of the developed products and some examples (garments and creams). A.) Enthalpy of the thermal management garments with and without washing cycles. B.) Antioxidant properties (elastase inhibition) for the developed creams. C.) Antibacterial activity in the fabrics treated with essential oils nanocapsules, with washing cycles.

Creams with triggered release nanocapsules which contain a cocktail of vitamins and antioxidants for anti-ageing skincare were also developed, with proven antioxidant activity (Fig. 1B).

To prevent and mitigate bacterial infections on the skin, lotions and textiles with targeted release nanocapsules, which are loaded with essential oils were also developed. The textiles exhibited high antimicrobial activity (according to ISO 20743), even after several washing cycles (Fig. 1C).

The developed products were tested to assure the safety and biocompatibility of the end-user.

SKHINCAPS is a European project funded under the Horizon 2020 research and innovation programme under grant agreement no. 685909. The project consortium comprises 8 partners: 4 research organisations – CeNTI (PT, coordinator), UPC (ES), IVW (DE) and VTT (FI) – and 4 industries – Bionanoplus (ES), Devan Micropolis (PT), TELIC (ES) and Pro-Active (BE).

To learn more about the projects innovative solutions, please be our guest at the workshop “SKHINCAPS Goes to Market” that will be held in Brussels in September 2019 (more information on the project's website: [www.skhincaps.eu/](http://www.skhincaps.eu/)).

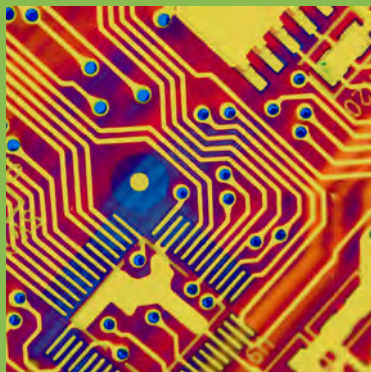
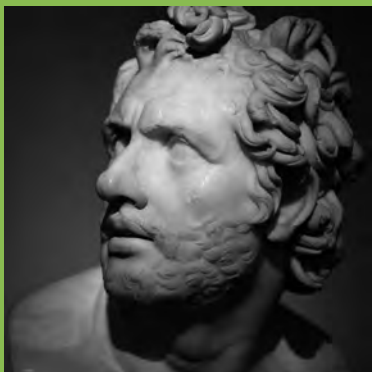


SKHINCAPS has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 685909



**Carla Silva, Project Coordinator**  
**Chief Technology Officer at CeNTI**  
 CeNTI – Centre for Nanotechnology and Smart Materials  
 Tel: +351 252 104 152  
[csilva@centi.pt](mailto:csilva@centi.pt)  
[www.centi.pt](http://www.centi.pt)  
[www.twitter.com/CENTI\\_PT](https://twitter.com/CENTI_PT)





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# UK priorities for science, research and innovation

The UK is focusing on international partnerships and ground-breaking sector deals in order to remain a global leader in science. Here, we find out about the work of Chris Skidmore MP, the UK's Minister for Universities, Science, Research and Innovation and the Office for Life Sciences

**T**he UK Government has launched a modern Industrial Strategy as part of a long-term plan to transform the economy and build a Britain “fit for the future”.

The strategy identifies five foundations of productivity and measures to realise them:

**Ideas:** Raising total research and development investment to 2.4% of GDP by 2027 and investing £725 million in new Industrial Strategy Challenge Fund programmes to capture the value of innovation.

**People:** Establish a world-leading technical education system; invest £406 million in maths, digital and technical education to help address the shortage in STEM skills; and create a new National Retraining Scheme.

**Infrastructure:** Increase the National Productivity Investment Fund to £31 billion; support electric vehicles through £400 million for charging infrastructure; and provide over £1 billion to boost digital infrastructure, including £176 million for 5G.

**Business Environment:** Launch Sector Deals for life sciences, construction, artificial intelligence (AI) and the automotive sector to boost productivity; drive over £20 billion of investment in innovation and high potential business; and launch a review of how to best support the growth of SMEs.

**Places:** Agree on Local Industrial Strategies; create a £1.7 billion Transforming Cities fund to improve intra-city transport; and provide £42 million to pilot a Teacher Development Premium.

**International partnerships to drive growth**  
In May, Chris Skidmore MP, the UK's Minister for Uni-

versities, Science, Research and Innovation, launched a new International Research & Innovation Strategy, underlining a commitment to worldwide partnerships as part of the Industrial Strategy's ambition to ensure the UK remains a world leader in emerging technologies.

The strategy was unveiled at the EUREKA Global Innovation Summit, the flagship event of the UK chairmanship of EUREKA, an intergovernmental body that supports international cooperation in research, development and innovation, where more than 1,700 business people and innovators from 65 countries met to exchange ideas and develop new ways of working to encourage global economic growth.

Skidmore announced a £4 million funding competition for UK participation in EUREKA projects that aim to speed up the delivery of innovations to market and to boost networking between innovators and business.

The calls for competitions include:

**GlobalStars (£1 million):** The GlobalStars funding competition between Singapore, the Netherlands and the UK is focused on medical technology, smart mobility and logistics and advanced manufacturing.

**Smart Manufacturing Cluster (£2 million):** Applicants have been invited to submit R&D and innovation project proposals in the area of advanced manufacturing applications and technologies.

**AI and Quantum (£1 million):** Collaboration between Austria, Belgium, Canada, Israel, Denmark, Spain, Switzerland, South Korea, Turkey and the UK.

Skidmore said: “Science and innovation have no borders and this new strategy reflects our aspiration to





see the UK draw systemically on research and innovation collaboration to build its economic growth while tackling global challenges. We've already backed this ambition by committing £7 billion over five years by 2022."

The International Research & Innovation Strategy will be delivered through the UK Science & Innovation Network, which has around 110 officers in over 40 countries and territories around the world. <sup>(1)</sup>

## Life sciences

Another key focus of the Industrial Strategy is the UK's life sciences sector, which contributes £70 billion to the economy and employs more than 240,000 scientists and staff.

Life sciences received one of the first Sector Deals in December 2017, which included commitments to the UK by 25 global organisations, including a major investment by healthcare firm MSD to develop a world-leading life sciences discovery research facility and headquarters in the UK, supporting 950 jobs.

In December 2018, a second life sciences Sector Deal was published, which included over £1.3 billion in inward investment from the sector.

A cornerstone of the deal is a major study, backed by up to £79 million of government funding, that will collect data from five million healthy volunteers to develop new diagnostics tests using AI.

Sir John Bell, the UK's Life Sciences Champion, says: "We all know someone who we love who has suffered the effects of a devastating disease. If we can detect illnesses like cancer, Alzheimer's and heart disease before symptoms present, we can open doors to transform treatment and save lives.

"I am honoured to be leading the Accelerating Detection of Disease project, which will bring together doctors, industry experts and leading charities, including Cancer Research UK, the British Heart Foundation and Alzheimer's Research UK.

"It is this kind of revolutionary work which will help people get the right treatment before they get ill and it is my ambition that this will give more of us more years of healthy life." <sup>(2)</sup> ■

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# The promises and challenges of biomodifying technologies for the UK

Michael Morrison, Senior Researcher in Social Science at the Centre for Health, Law and Emerging Technologies (HeLEX), University of Oxford, sheds light on the promises, as well as the challenges when it comes to biomodifying technologies for the UK

One of the most promising areas of medical innovation is the idea of using our own cells and genes to treat disease. Scientists have been studying these possibilities under a variety of labels including 'gene therapy', 'tissue engineering' and 'regenerative medicine' for several decades. Despite this work, only a limited number of cell or gene-based therapies are currently available, with the most common procedure being the use of stem cells from bone marrow or umbilical cord blood to replenish the body's immune system after chemotherapy.

The UK has a well-established life sciences sector, with world-class academic research, a commercial sector that ranges from pharmaceuticals to data analysis and contract manufacturing, a National Health Service with multiple research-intensive hospitals and an established system of regulatory oversight. It is in many respects an advantageous location for developing new regenerative medicines.

However, there are a number of challenges in bringing innovative science to the clinic, a process known as 'translation', especially in a sector still largely designed around conventional drugs, medical devices or surgical procedures<sup>1</sup>. Therapies based on living tissues are more difficult to manufacture and standardise than

traditional drugs. They change in response to their environment and often vary from batch to batch making it harder to establish quality and safety. They may require new clinical skills and working arrangements to deliver and there is a lack of proven models for balancing viable commercial production with sustainable healthcare costs.

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**"While it is difficult to predict exactly what new applications of each technology will emerge and bioprinting, gene editing and iPSC are at different stages of maturity, reimbursement and data collection and regulation are likely to be significant challenges."**

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In this context, robust, innovative science is clearly important but it is not sufficient by itself to deliver workable new therapies that deliver tangible patient benefit. The process of translating knowledge into novel medical products and services is necessarily a collaborative endeavour. It requires academics, companies, healthcare professionals, regulators, funding agencies, hospital managers and health economists working together to develop solutions.

Infrastructure is important, as recent investment by the UK Government in the Cell and Gene Therapy Catapult centre and the three Advanced Therapy Treatment Centres (ATTCs)

acknowledges. This investment is further complemented and on occasion informed, by social science studies of innovation and clinical translation which can clarify points of alignment or tension between the priorities of different stakeholders, identify organisational factors that support or inhibit the uptake of new medical technologies and help to understand how regulations impact academic, commercial and clinical activity<sup>1,2,3</sup>.

A number of recent discoveries have enabled researchers to modify living biological tissue in novel ways that raise the prospect of increasingly customised, patient-orientated treatments. Three contemporary examples of such 'biomodifying technologies' are; 'gene-editing' using tools like CRISPR-Cas9\* to modify DNA, induced pluripotent stem cell technology that allows an ordinary skin or blood cell to be turned into a stem cell capable of producing any tissue type in the human body, and the emergence of bioprinting which can produce three dimensional structures made from living tissues. Each of these are 'gateway' technologies: versatile, comparatively easy to use, with advantages in speed or precision over existing tools and having a broad range of potential applications. Translating these technologies into new medicines holds promise for addressing significant unmet medical need; potential cures

for genetic diseases, tissue-based therapies for degenerative conditions and replacement organs to ease the pressure on transplant waiting lists. 3D bioprinting, gene editing and induced pluripotent stem cells (iPSC) also represent potential 'personalised' medicines, tailored to match the biology of an individual patient or made from a patient's own modified cells.

**“One of the most promising areas of medical innovation is the idea of using our own cells and genes to treat disease. Scientists have been studying these possibilities under a variety of labels including ‘gene therapy’, ‘tissue engineering’ and ‘regenerative medicine’ for several decades.”**

Two projects, 'Biomodifying technologies and experimental space', funded by the Economic and Social Research Council and 'BIOGOV: Governing Biomodification in Life Sciences Research' (Leverhulme Trust), are building on previous social and legal research<sup>2,3</sup> to identify critical issues for the development of customised cell and gene therapies in the UK. While it is difficult to predict exactly what new applications of each technology will emerge and bioprinting, gene editing and iPSC are at different stages of maturity, reimbursement, data collection and regulation are likely to be significant challenges. Biomodifying therapies are expensive and often target rare disease or the most severely affected patients with more common conditions. In the U.S., the recently-approved gene therapy for muscular atrophy Zolgensma™ is the world's most expensive drug at \$2.125 million per treatment. Personalised or

customised therapies only exacerbate these tendencies.

The prospect of a spate of ultra-expensive biomodifying therapies coming to market is likely to threaten fair access provisions for any healthcare system based on social justice and need rather than the ability to pay. There is, therefore, a tension between the state's role in promoting the UK as a supportive environment for innovative life sciences research and its need to ensure a sustainable National Health Service by controlling healthcare expenditure. The UK's National Institute for Health and Care Excellence (NICE) 'highly specialised technologies' pathway allows significantly higher costs for complex treatments for rare conditions. However, current assessments are based on several years of data from clinical trials, which struggle to capture potentially life-long effects of cell and gene therapies. Small patient populations also means the trials often involve relatively small numbers of participants. Making biomodifying therapies a reality may require complementary innovations in healthcare reimbursement models, new forms of evidence such as large-scale open access studies of the long-term impacts of cell and gene therapies that allow safety and efficacy to be evaluated and reviewed over lifetimes, and evolving regulation whose impact can be assessed and, if appropriate, revised in a timely fashion<sup>4</sup>.

*\* CRISPR stands for Clustered Regularly Interspersed Short Palindromic Repeats. It is a molecule that can be designed to identify and bind a particular stretch of*

*DNA, which is then cut by the ‘molecular scissors’ of the Cas9 protein.*

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**Michael Morrison**  
**Senior Researcher in Social Science**  
 Centre for Health, Law and Emerging Technologies (HeLEX), University of Oxford  
[michael.morrison@dph.ox.ac.uk](mailto:michael.morrison@dph.ox.ac.uk)  
<https://www.ndph.ox.ac.uk/research/centre-for-health-law-and-emerging-technologies-helex>  
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# Boosting culture, heritage, science and innovation in the Netherlands

The Government of the Netherlands has launched a major funding drive to support the arts, culture and heritage sectors in the Netherlands, as well as in science and innovation, headed up by Minister of Education, Culture and Science, Ingrid van Engelshoven

By way of background, we know that Ingrid van Engelshoven was appointed as Minister of Education, Culture and Science in the third administration of Dutch Prime Minister, Mark Rutte in October 2017.

She began her career in 1989 as a policy officer for the Democrats '66 parliamentary party in the House of Representatives and served as its Secretary from 1994 to 1996. She then worked as an adviser to the Netherlands Bar Association before acting as Head of Strategy at the Ministry of Transport, Public Works & Water Management from 2000 to 2004 and Director of the Foundation for Responsible Alcohol Consumption from 2004 to 2008.

In 2010, she joined the municipal executive of The Hague with responsibility for education and public services before becoming a Member of Parliament in 2017. The Ministry of Education, Culture & Science works to create a smart, skilled and creative environment for the Netherlands.

Its key objectives are to ensure:

- Everyone gets a good education
- Everyone is prepared for personal independence and responsibility
- Everyone has the opportunity to experience and enjoy culture
- Teachers, artists and scientists have the right conditions to be able to carry out their work.

This article will look at what the Government of the Netherlands is doing to invest in some of these areas, including science and innovation.

## Investment in art, culture and heritage

In March 2018, van Engelshoven announced a major initiative designed to support these goals, with plans to invest €80 million a year on art and culture, as well as a further €325 million to ensure future generations can continue to enjoy heritage sites.

A joint talent programme has been created to help a new generation of artists and “culture makers” to develop and flourish. The Government of the Netherlands invested €2.7 million in the programme in 2018, rising to €4.9 million in 2019 and subsequent years.

To boost arts and cultural education, the Government of the Netherlands committed €2.1 million in 2018, rising to €4.9 million in 2019 and subsequent years, to enable all schoolchildren to visit the Rijksmuseum, the national Dutch museum, or another museum during school time.

In addition, the Government of the Netherlands is expanding its music education grant scheme from 1,000 to 1,600 schools. Schools will also be challenged to introduce their pupils to “the more provocative and confrontational side of culture”, with the Government of the Netherlands investing more in Amsterdam’s EYE film museum and youth theatre companies.<sup>(1)</sup>

## National Science Agenda

Did you know that Dutch scientific research ranks among the best in the world? As such, the Government of the



Netherlands is taking measures to keep it at the top.

Certainly, Ingrid van Engelshoven plans substantial investment in science to provide more scope for innovative research. Going into further detail, we know that an additional €70 million was made available in 2018, with additional increases of €108 million in 2019 and €130 million per year from 2020. The National Science Agenda brings together universities; other knowledge institutions like the Royal Netherlands Meteorological Institute (KNMI) and the Netherlands Organisation for Applied Scientific Research (TNO), not to mention a number of stakeholders and organisations from the private sector to work on scientific breakthroughs and social issues.

Examples include research include cybersecurity, sustainable food, water management, safe societies, inequality of opportunity and even the origins of life. “This type of cooperation is vital for tackling social issues effectively. And it gives science a greater impact,” said Ms Van Engelshoven.

### Science and technology

The Government of the Netherlands acknowledges that the science and technology sector faces significant challenges and as such, we know that additional funds are being made available to increase the scope of high-quality research and graduate training in the sector. The funding will offer more scope for investment in humanities and social sciences, two areas that play a vital role in fields, such as conflict mediation, healthcare and sustainability,

Looking at the wider picture, we know that the Netherlands is eager to increase the role it plays in world-class international research facilities, such as ESO and CERN and as such, €60 million will be provided for this purpose. It's worth adding here that Dutch participation in new research projects can foster further chances for the private sector to be involved in who can build the required facilities.

### Supercomputer

In the space available, I wanted to mention that these exciting plans also include a significant focus on digital research infrastructure, something that can improve the uptake of research and optimise access to data ('open science') in the pursuit of seeking solutions to

scientific, social and economic issues. From 2018 onwards, an annual budget of €20 million has been set aside for digital research infrastructure, with the biggest part of this targeted at high- performance computing. As I am sure you know, supercomputers have enormous storage and computational capacities, which help facilitate research into big data. In the view of the Ministry of Education, Culture & Science, this type of research is vital to improve our understanding of a number of areas, such as climate change. Certainly, supercomputers also play a growing and essential vital role in making data accessible and fit for practical application in health and social care plus other sectors.

### Applied research

Finally, let's turn our thoughts to applied research and it's worth noting that the Government of the Netherlands wants to strengthen this in universities and has, therefore, agreed for extra funding to be made available for this purpose, slowly increasing to €25 million from 2020. This work is most useful because universities of applied science bridge the gap between theoretical knowledge and practical innovation. Because of this, they are ideally placed to make a major contribution to research that focuses on innovation and social issues – and they also have a considerable impact on a regional basis. <sup>(2)</sup> ■

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# Bioinorganic studies of multi-electron redox processes

Bioinorganic studies of multi-electron redox processes, from fundamental research to applications in a future renewable energy infrastructure

**D**eforestation that started during the industrial revolution and the consumption of fossil fuels have led to a rapid increase in carbon dioxide in the atmosphere from 250 ppm to over 400 ppm over the last 150 years.<sup>1</sup> This increase in carbon dioxide concentrations coincides with a global temperature rise. Both temperature and carbon dioxide concentrations increase orders of magnitude faster than they have ever done before in the last 400,000 years. These rapid changes are placing enormous stress on nature and agriculture at locations that are under threat of desertification.

Expectations are that global energy consumption will substantially increase within the next 25 years due to the massive migration of people from the lower class to the middle class. It is, therefore, important that renewable energy is implemented into the worldwide energy infrastructure at a terawatt scale.

It is also important that exploration of renewable energy does not go at the cost of nature, biodiversity or agricultural grounds, which are already under an enormous amount of stress. Solar and wind energy are most promising but suffer heavily from intermittency problems. It is, therefore, important to buffer the demand and availability of electricity through storage.

Herein it is important to note that batteries are expensive and heavy for the amount of electricity they can store.<sup>2</sup> Ideally, energy is best stored as a high-density fuel that is produced by, for example, the reduction of water to produce hydrogen gas in electrolyzers. In addition, liquid carbon-based fuels can be obtained by reduction of carbon dioxide. Electricity can be regenerated in times and places of need by consumption of the synthetic fuel in fuel cells, thereby closing a fully sustainable cycle.

Nature has already found a way to convert solar energy into chemical bonds billions of years ago. Light is captured during photosynthesis and its energy used to synthesise NAD(P)H and ATP, while simultaneously producing oxygen. It is the synthesis of oxygen, which is produced simultaneously with hydrogen, that is the key bottleneck in the electrolysis of water. The synthesis of ATP is essential since it is the energy source for all chemical processes taking place in biology, whereas NAD(P)H acts as a transporter of reducing equivalents. At the cost of ATP and NADPH, carbon dioxide is captured by RuBisCo during the Calvin cycle, which is an entry into several metabolic pathways, which includes the synthesis of glucose.

Hydrogen can be produced in biology at the cost of reducing equivalents by hydrogenases, while nitrogenases are

capable of synthesising ammonia from nitrogen. Ammonia is the feedstock for the synthesis of every nitrogen-containing molecule in biology and therefore also an excellent fertiliser. At present, more than 1% of all energy consumed by mankind is due to the Haber Bosch synthesis of ammonia by the chemical industry.<sup>3</sup>

The Krebs cycle is the metabolic pathway for the reduction of glucose, which results in the eventual synthesis of ATP via a series of redox processes, which involves the reduction of oxygen by cytochrome c oxidase. The reduction of oxygen is a major bottleneck in fuel cell technology.

The catalysts that are currently employed in electrolyzers and fuel cells are relatively simple in terms of structure. The catalysis community has learned to produce and consume oxygen with high catalytic rates at catalytic sites that have a very long lifespan.

However, these catalysts do suffer from efficiency problems and require a substantially higher voltage than strictly necessary from a thermodynamic point of view.<sup>4</sup> It is, therefore, interesting to note that Laccase, another enzyme that is capable of reducing oxygen to water, can operate at substantially more favourable potentials from an energy efficiency point of view.<sup>5</sup> However, the lifetime



under operating conditions and the sheer size of the enzyme – and thereby the electrode surface area that one would need – prevent the practical use of such enzymes in fuel cells.

In order to produce better catalytic systems for the energy conversion reactions that are of interest for our energy infrastructure, it is important to understand what principles make the enzymatic systems superior. Many years of very fundamental bioinorganic chemistry have led to the identification of key design principles of, among others, the oxygen reduction by cytochrome c oxidase, water oxidation by photosystem and hydrogen evolution by hydrogenases.

Also, massive improvements to our fundamental understanding of the nitrogen reduction reaction by nitrogenases have been made. This, in turn, has led to an entire scientific field that tries to apply these design principles in proof-of-principle devices that use electricity or even direct sunlight to fix energy in the form of chemical bonds.

In the laboratory of Hetterscheid, the electrocatalytic reduction of oxygen and the oxidation of water are studied in the presence of molecular catalysts that are inspired by the design principles taken from nature. The main focus of research is not to replicate the exact same structure as the active site cofactors present in enzymes. In

fact, typically accurate mimics of the active site of enzymes show poor catalytic performance in the absence of the peptide environment due to changes in the dynamics and coordination sphere of the catalytic site. Mimicking these design principles from a function-point-of-view, however, has led in several occasions to catalytic systems that display significantly higher turnover frequencies than the enzymatic systems. The next challenge is to implement such bio-inspired catalytic systems into a practical application.

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**Universiteit  
Leiden**

#### **Professor Dennis Hetterscheid**

Leiden Institute of Chemistry (LIC)

Tel: +31 715 274 545

[d.g.h.hetterscheid@chem.leidenuniv.nl](mailto:d.g.h.hetterscheid@chem.leidenuniv.nl)

[www.universiteitleiden.nl/en/science/chemistry](http://www.universiteitleiden.nl/en/science/chemistry)



# Advancing basic chemical research while developing a globally competitive workforce

Carol Bessel and Melissa Olson from National Science Foundation's Division of Chemistry (CHE) reveal the organisation's goal of advancing basic chemical research while also developing a globally competitive workforce

The Division of Chemistry (CHE) at the National Science Foundation is committed to the goal of advancing basic chemical research while also developing a globally competitive workforce. The pursuit of fundamental chemical science, however, is not just bound to the lab. Rather, it serves to address and solve some of the most pressing societal challenges.

CHE actively solicits and funds projects that design and develop sustainable chemistry pathways from synthesis to recycling; advance algorithms and novel qubit structures for quantum computing; accelerate and complement chemical discovery with data mining and artificial intelligence (AI); and seek to understand and engineer the biochemistry governing life processes such as in synthetic biology, epigenetics and studies of the microbiome. Because each of these grand challenges straddles disciplinary lines and national borders, CHE also promotes interdisciplinary and international teams. Any real solution to these grand challenges also requires public support, calling chemists out of the lab to communicate, interact and broaden participation.

Chemistry forms the basis of nearly all consumer products, from the long, messy chains of carbon atoms in plastics, to the atomically precise molecules in pharmaceuticals with chiral structures. While these products prove incredibly useful and sometimes lifesaving, their entire 'life cycle', from cradle to grave to cradle, must be considered. The desirable durability of plastics leads to their problematic persistence in the environment, as witnessed in plastic 'islands' in the oceans. Aiming to reduce plastics in the environment, CHE funds projects exploring catalysis for novel polymers designed to be chemically or mechanically degraded, biodegraded and/or upcycled into new consumer goods. The atom-

level precision required in fine chemicals often leads to many-step reactions and purification processes, each consuming energy or generating solvent waste. Creating sustainable synthetic methods, real-time characterisation and facile separations are priorities for CHE. Organic electrosynthesis is an especially opportune area for collaboration, especially with engineering partners such as the Division of Chemical, Bioengineering, Environmental and Transport Systems (CBET) Division at NSF. CHE also hopes to strengthen this field through international partnerships in the future.

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**“One of the first, large-scale projects to develop and adopt big data concepts was the Human Genome Project. Sequencing the human genome was a momentous achievement, but it also raised a myriad of additional, interesting scientific questions.”**

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While developing sustainable chemistry is imperative, fundamental research underpins all advances. This includes the particle-to-particle and atom-to-atom interactions defined by quantum mechanics. Through Quantum Leap, one of NSF's Big Ideas to guide the next decade of research, CHE supports research addressing and exploiting a wide variety of quantum phenomena, from spectroscopy with entangled light to controlling electronic spin for molecular qubit design. This work blurs interdisciplinary lines and requires a new approach to workforce development, so CHE partners with eight other NSF divisions for projects such as QISE-NET, which builds 'Triplets' between students, academic mentors and industrial mentors and Quantum Leap Challenge Institutes, large-scale interdisciplinary research projects that seek to advance the frontiers of quantum computation, communication, simulation and/or sensing.



While the development of quantum computing harnesses the smallest of phenomena, chemists are also turning to big data. With the generation and assemblage of mass amounts of computational and experimental data, exploration of new chemistries can be guided and accelerated with tools such as data mining, machine learning and cheminformatics. CHE supports the development and application of these tools through the Data-Driven Discovery in Chemistry program and through the Harnessing the Data Revolution Big Idea. These projects touch all fields in chemistry, from the [optimization of chemical reactions](#) in microdroplets to the search for [protein folding guidelines](#). These techniques can require programming and statistical analysis that go beyond the bounds of traditional chemistry. To foster new collaborations between mathematicians and chemists, CHE has worked with the Division of Mathematical Sciences to sponsor an Innovation Lab bringing together investigators from both disciplines to innovate and generate new ideas and project proposals.

One of the first, large-scale projects to develop and adopt big data concepts was the Human Genome Project. Sequencing the human genome was a momentous achievement, but it also raised a myriad of additional, interesting scientific questions. Another NSF Big Idea, Understanding the Rules of Life, aims to tackle one of these questions – how to predict phenotype (observable characteristics) from genetic information. CHE plays a significant role in answering this question, especially as it is reduced to molecular interactions and chemical responses. These projects include [designing platforms for the study of macromolecules](#) that reproduce the crowded conditions in cells and [synthesizing artificial organelles](#), both of which are co-funded with CBET or the Directorate for Biological Sciences.

While poised to address the scientific aspects of these challenges, chemistry needs an informed and active public to help fund or implement any solution. Every award that CHE makes requires investigators to consider the broader impacts of their work, which includes the impacts on the public. Chemistry encourages investigator efforts aimed at education, for example, [Energy and U](#), a collaboration between the chemistry and theatre departments at the University of Minnesota that teaches students about the laws of thermodynamics. Other investigators develop entirely new media for education, such as [3D printed protein structures](#) to help teach blind students about protein dynamics. CHE also encourages chemists to engage in efforts outside academe, offering support for graduate students to pursue internships in industry or government laboratories.

Though CHE strategically supports the programs and initiatives mentioned above, it continues to support basic chemical research of all kinds. Chemistry remains a powerful tool, both inside of the lab when exploring fundamental phenomena and beyond the lab, improving the world around us. ■

**Carol Bessel**  
Acting Division Director

**Melissa Olson**  
Presidential Management Fellow

Division of Chemistry (CHE)  
National Science Foundation (NSF)  
Tel: +1 703 292 5111  
info@nsf.gov  
<https://www.nsf.gov/div/index.jsp?div=CHE>  
[www.twitter.com/NSF](https://twitter.com/NSF)

# Chemistry and biochemistry: Sugar conformational equilibria and dynamics

Ian Carmichael<sup>a</sup>, Robert J. Woods<sup>b</sup> and Anthony S. Serianni<sup>c</sup> share their expertise on an aspect of chemistry and biochemistry that concerns circular statistics and NMR which reveal sugar conformational equilibria and dynamics

Carbohydrates are talented actors on the biological stage. In addition to their roles in metabolic energy production, they are found on cell surfaces, conjugated to membrane-associated proteins and lipids and as such serve as ligands of extracellular receptors that mediate cellular processes such as cell-cell recognition, bacterial and viral infection, immunity and intracellular trafficking.<sup>1</sup> Sugar conformational equilibria and dynamics can be complex in that saccharides contain multiple, flexible elements that collectively determine their overall shapes in solution. The properties of these flexible elements are often correlated and include pyranosyl ring pseudorotation, exocyclic hydroxyl and hydroxymethyl side-chain rotation, *N*- and *O*-acetyl side-chain motions and motions about *O*-glycosidic linkages in oligosaccharides (Figure 1).

For decades, NMR spectroscopy has been used to characterise these solution behaviours by measuring, for

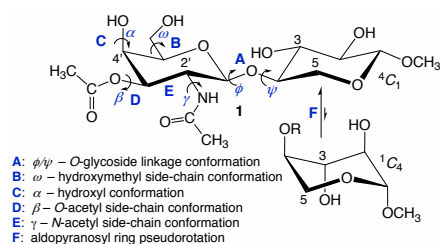


Figure 1. Some common conformational elements in saccharides, illustrated in the disaccharide, methyl 2-acetamido-2-deoxy-3-*O*-acetyl- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)- $\beta$ -D-xylopyranoside (1). [\[Click image to view full size\]](#)

example, nuclear Overhauser effects (NOEs), scalar couplings, residual dipolar couplings and nuclear spin relaxation.<sup>2</sup> These parameters yield valuable insights into saccharide behaviours but cannot provide, independently, continuous conformational models; their interpretations rely on input from computed energies and/or molecular dynamics (MD) simulations. This dependence is troublesome because (a) saccharide computed energies are error-prone due to the influences of hydroxyl group conformation and/or solvation and (b) saccharide MD simulation models are very difficult to validate experimentally. Current research relies on MD to provide information on saccharide conformation and dynamics in the absence of definitive experimental evidence that MD models provide accurate pictures of solution behaviour.

A new development in the analysis of NMR scalar couplings promises to break the circular arguments and provide independent experiment-based models of saccharide solution behaviour. The technique, known as MA'AT analysis,<sup>3–6</sup> yields outputs very similar to those provided by MD, allowing direct superimposition of MA'AT-derived models on those obtained by MD simulations.

MA'AT analysis involves six steps (Figure 2), illustrated in the modelling

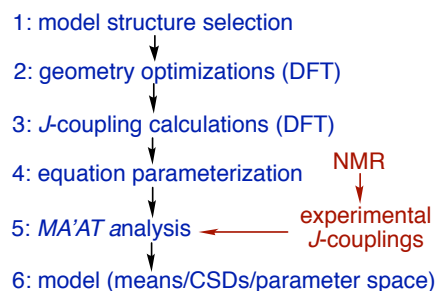


Figure 2. Flow chart for MA'AT analysis. After model selection (1), DFT is used to conduct geometry optimizations (2) and to calculate *J*-couplings (3). Parameterized *J*-coupling equations (4) are used along with experimental *J*-couplings as input to the MA'AT program (5). Conformational models are obtained as output (6).

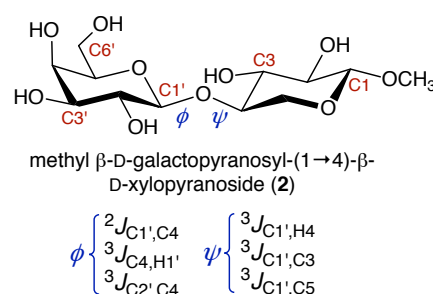
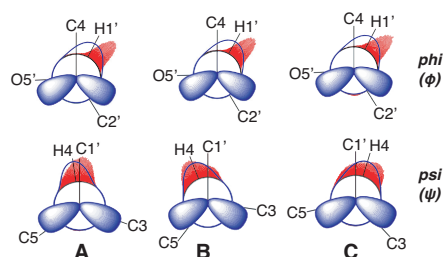


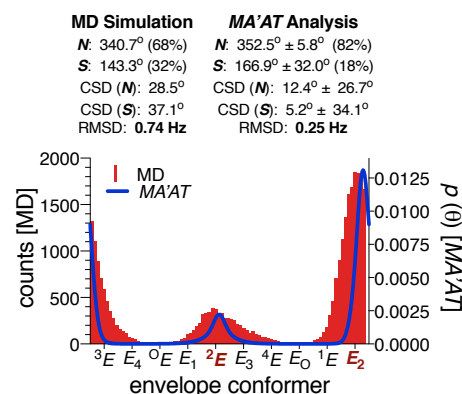
Figure 3. Definitions of  $\phi$  and  $\psi$  in disaccharide 2 and redundant NMR spin-couplings sensitive to these torsion angles.

of the *phi* ( $\phi$ ) and *psi* ( $\psi$ ) *O*-glycosidic torsion angles of disaccharide 2 (Figure 3). The structure of 2 is encoded in the z-matrix input to Gaussian.<sup>7</sup> Ensembles of redundant *J*-couplings sensitive to  $\phi$  and  $\psi$  are required and in this case, three *J*-values are sensitive to each angle (Figure 3). Rotating  $\phi$  and  $\psi$  in the *in silico* model of 2 through 360° in 15° increments produces 576 conformers and each is geometry optimised using density functional theory (DFT) (Step 2). The six *J*-couplings are calculated in





**Figure 4.** MA'AT and MD analysis of  $\phi$  and  $\psi$  in (A)  $\beta$ Gal-(1 $\rightarrow$ 4)- $\beta$ GlcOCH<sub>3</sub> (**3**), (B)  $\beta$ Gal-(1 $\rightarrow$ 4)- $\beta$ AlloCH<sub>3</sub> (**4**) and (C)  $\beta$ Gal-(1 $\rightarrow$ 4)- $\beta$ XylOCH<sub>3</sub> (**2**), shown as Newman projections down each C–O bond. Histograms (red) were obtained from 1- $\mu$ s aqueous MD simulations on which are superimposed distributions (blue) determined from MA'AT analysis. Data were taken from ref. 4. [\[click image to view full size\]](#)



**Figure 5.** MA'AT analysis of methyl  $\beta$ -D-ribofuranoside (**5**), yielding a two-state  $E_2/{}^2E$  model (blue curve) superimposed on the model predicted by a 1- $\mu$ s aqueous MD simulation (red histogram). Fitting statistics for both models are shown above the plot. [unpublished] [\[click image to view full size\]](#)

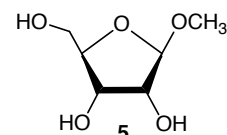
the 576 conformers (Step 3) and the dependencies are encoded into parameterised equations that generally take the form,  $J_{\text{exp}} = A + B \cos \theta + C \cos 2\theta + D \sin \theta + E \sin 2\theta$  (Step 4). The experimental  $J$ -couplings are measured in **2** and the experimental values and parameterised equations are used by the MA'AT program (Step 5), which applies a Monte Carlo search and circular statistics to fit the experimental  $J$ -values to conformational models of  $\phi$  and  $\psi$  (Step 6). In this case, only single-state models of  $\phi$  and  $\psi$  pertain due to the small number of observables, but multi-state models can be tested if the number of experimental  $J$ -couplings is sufficient (see below).

MA'AT outputs include the mean values of  $\phi$  and  $\psi$  and circular standard deviations (CSDs) of these mean values, the latter providing information on the librational character of each torsion angle.

The application of MA'AT to  $\phi$  and  $\psi$  in **2** gives the single-state models shown in Figure 4(C), superimposed on those determined by aqueous MD simulation. The models are in good agreement for  $\psi$ , but differ for  $\phi$ . The sensitivity of the method can be demonstrated by examining  $\beta$ Gal-(1 $\rightarrow$ 4)- $\beta$ GlcOCH<sub>3</sub> (**3**) and  $\beta$ Gal-(1 $\rightarrow$ 4)- $\beta$ AlloCH<sub>3</sub> (**4**) in a similar manner (Figure 4A and B). MA'AT models of  $\psi$  in **3** and **4** recapitulate the MD models well, but discrepancies in  $\phi$  are observed similar to that found for **2**.<sup>4</sup>

MA'AT analysis can be applied, in principle, to any conformational element in any molecule if multiple, redundant  $J$ -values exist, can be measured reliably and can be parameterised. For example, the conformational behaviour of the furanose ring in methyl  $\beta$ -D-ribofuranoside (**5**) was investigated using nine intra-ring  $J_{\text{HH}'}$ ,  $J_{\text{CH}}$  and  $J_{\text{CC}}$  values to give a two-state  $E_2/{}^2E$  pseudorotational model that recapitulates, although not exactly, that obtained by MD simulation (Figure 5).

MA'AT analysis was first described in 2017,<sup>3–4</sup> and its power and applicability have yet to be fully illuminated. It is expected that the method will lead to improved MD force-fields, especially in cases where solvent effects play key roles in determining conformational preference in solution. In addition, while current applications have been limited to saccharides, studies of oligopeptides and oligonucleotides and perhaps larger molecules, are anticipated.



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[<sup>a</sup>Radiation Laboratory and <sup>c</sup>Department of Chemistry and Biochemistry, University of Notre Dame, Notre Dame, IN 46556-5670 USA; [<sup>b</sup>Complex Carbohydrate Research Center, University of Georgia, Athens, GA 30602 USA].

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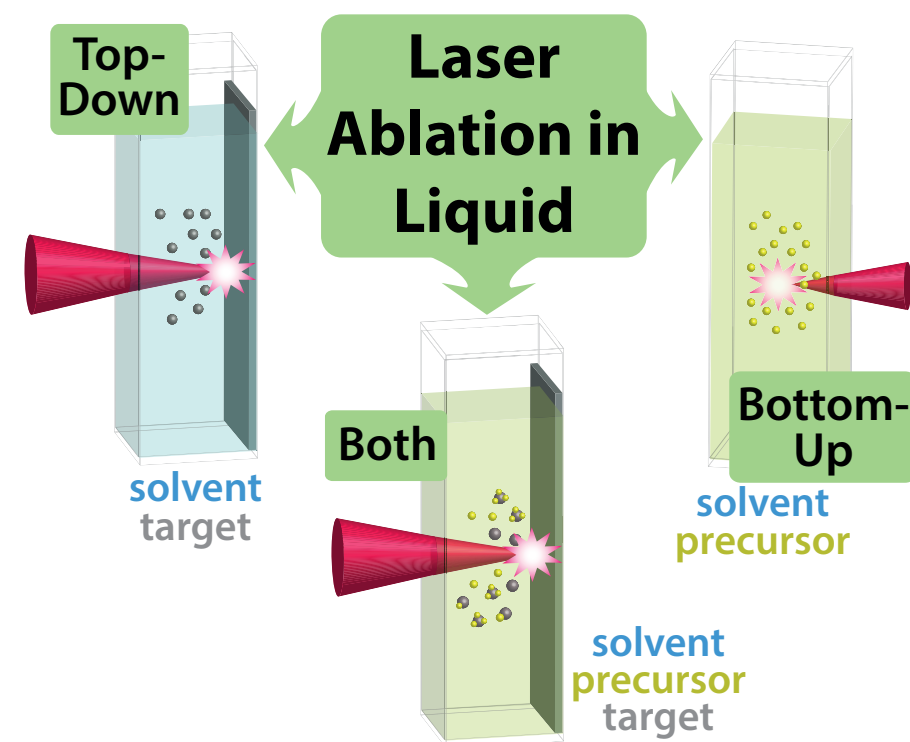
**Anthony S. Serianni**  
**Professor of Chemistry**  
**and Biochemistry**  
 University of Notre Dame  
 Tel: +1 574 631 7807  
 aseriann@nd.edu  
 nd.edu/~aseriann

# Chemistry focus: Advances in engineering functional nanomaterials research

Katharine Moore Tibbetts, Assistant Professor at Virginia Commonwealth University, shares with us her expertise on advances in engineering functional nanomaterials, an area of chemistry research that has benefitted society in various ways

Nanomaterials have well-defined structures on length scales smaller than 100 nm (1,000,000,000 nm = 1 m), close to the size of individual atoms and molecules. These small sizes impart unique optical, electronic and catalytic properties that cannot be obtained in bulk materials. In recent years, advances in engineering functional nanomaterials have revolutionised applications from cancer therapy and drug delivery to industrial catalysis and solar fuel generation. Nanomaterials are, therefore, enabling 21st century technologies to meet major challenges to society such as sustainable energy development.

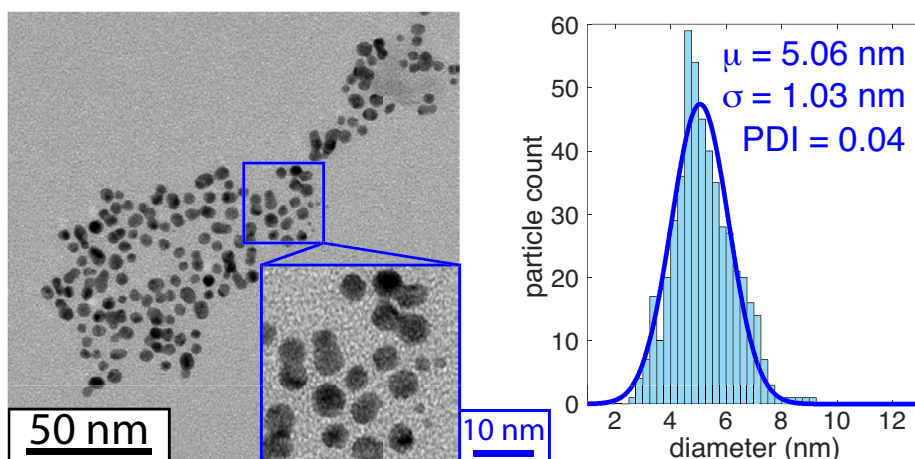
While immense progress in synthetic methods over the past three decades has made it possible to create tailored nanomaterials with well-defined sizes and compositions, the most commonly used wet-chemical synthetic methods suffer from two major drawbacks. First, they typically require excessive quantities of toxic chemicals that generate large amounts of waste. For instance, the standard procedure for making ultrasmall <2 nm gold nanoparticles requires a 10-fold excess of reducing agent and at least 3-fold excess of capping ligand. Second, the capping ligands that are needed to control nanoparticle sizes can hinder the use of these nanoparticles in applications. For instance,



cytotoxic ligands must be removed from metal nanoparticles prior to use in biomedical applications and organic ligands can block access to catalytically active surface sites in metal nanoparticle catalysts. As a result, "naked" nanoparticles with no capping ligands are highly desirable for these and other applications.

Laser ablation in liquid (LAL) has recently emerged as a versatile synthetic route to a variety of nanomaterials that overcomes the major drawbacks of wet-chemical synthesis. Instead of requiring a complex

mixture of toxic chemicals, LAL can produce nanomaterials using only water and solid or powdered target material. The lack of toxic chemical use and waste generation means that LAL methods satisfy the major principles of "green chemistry" and can become a platform for environmentally sustainable nanotechnology development. Moreover, nanoparticles synthesised by LAL often do not require capping ligands because they emerge electrostatically stabilised. As a result, LAL is a powerful method for producing naked nanoparticles uniquely suited to biomedical and catalysis applications.



These advantages of LAL coupled to advances in commercial pulsed laser technology have generated surging interest in LAL for nanomaterial synthesis. This interest is captured by the 30-fold increase in citations from an ISI Web of Knowledge search of “laser synthesis nanoparticles” from 563 in 2003 to 16,925 in 2018. LAL-synthesised nanomaterials show promise in applications such as electrochemical water-splitting, photocatalytic hydrogen generation and photothermal cancer therapy. While LAL manufacturing of nanomaterials at industrial scales is likely years away, grammes per hour production rates are now attainable with advanced high-repetition-rate lasers.

In LAL, a high-power pulsed laser is focused into a liquid medium or onto a solid-liquid interface (Figure 1). LAL encompasses both “top-down” and “bottom-up”, as well as combined approaches to nanomaterial synthesis. In top-down methods, an immersed solid or powder of the target material produces nanomaterials in the surrounding solution as atoms and clusters are blasted off of the surface or powder particles are fragmented in the laser focus. In bottom-up meth-

ods, a precursor such as a metal salt dissolved in solution produces nanomaterials through photochemical reactions of the precursor and solvent initiated by laser irradiation. Combined approaches involve immersion of a solid or powder in a precursor solution to produce composite nanomaterials from ablated material reacting with the precursor and solvent.

The top-down approach is by far the most widely used in the LAL community due to the low cost of solid materials relative to molecular precursors, simplicity of performing synthesis reactions and ability to manufacture large quantities of nanomaterial products. However, a significant drawback of top-down approaches is the often limited control over the size distributions of the resulting nanoparticles. For instance, gold nanoparticles have been synthesised by top-down ablation of gold foil for at least two decades, but even recent studies typically report asymmetric size distributions containing large >20 nm particles despite a mean particle size of 5 nm.

For applications where tight particle size distributions are needed, bottom-

up LAL synthesis represents a promising alternative. For instance, our laboratory recently reported uniform 5-nm gold nanoparticles using bottom-up photoreduction of the tetrachloroaurate salt in water using a commercial 532 nm Nd:YAG laser (Figure 2) <sup>(1)</sup>. While bottom-up LAL synthesis has received less attention than the common top-down methods, it represents a potential platform for tailoring photochemical reactions to attain exquisite control over the sizes and compositions of nanomaterials produced with LAL. Achieving this potential will require advances in understanding the photochemical reaction pathways that convert precursors in solution to nanomaterials, which is a primary goal of our laboratory’s research.

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**Katharine Moore Tibbetts**  
**Assistant Professor**

Virginia Commonwealth University  
 Tel: +1 804 828 7515  
 kmtibbetts@vcu.edu  
<https://chemistry.vcu.edu/people/faculty/tibbetts.html>



# Microfluidic devices: The future is here

Dr Stefan H. Bossmann and Dr Christopher T. Culbertson, Professors of Chemistry at Kansas State University, explain why microfluidic devices are in their view, the future

**M**icrofluidics is all about controlling the flow of liquids on the micro-scale. In microfluidics, tiny channels are etched onto circuit boards, smaller than a human fingernail, through which minuscule volumes of chemicals and other liquids can flow. One use of this technology is for everyday inkjet printers, where the channels help carefully control where the ink is sprayed in the printing process. These channels can also be merged, allowing two separate chemicals to mix and react, which is

why some of these microfluidic devices are sometimes known as the 'lab-on-a-chip'.

This team of investigators is led by Dr Christopher T. Culbertson and Dr Stefan H. Bossmann at Kansas State University. We are very excited by some of the possibilities that microfluidics and the lab-on-a-chip offer. In our highly interdisciplinary and collaborative project, our teams are working together to develop this technology into a miniature analysis

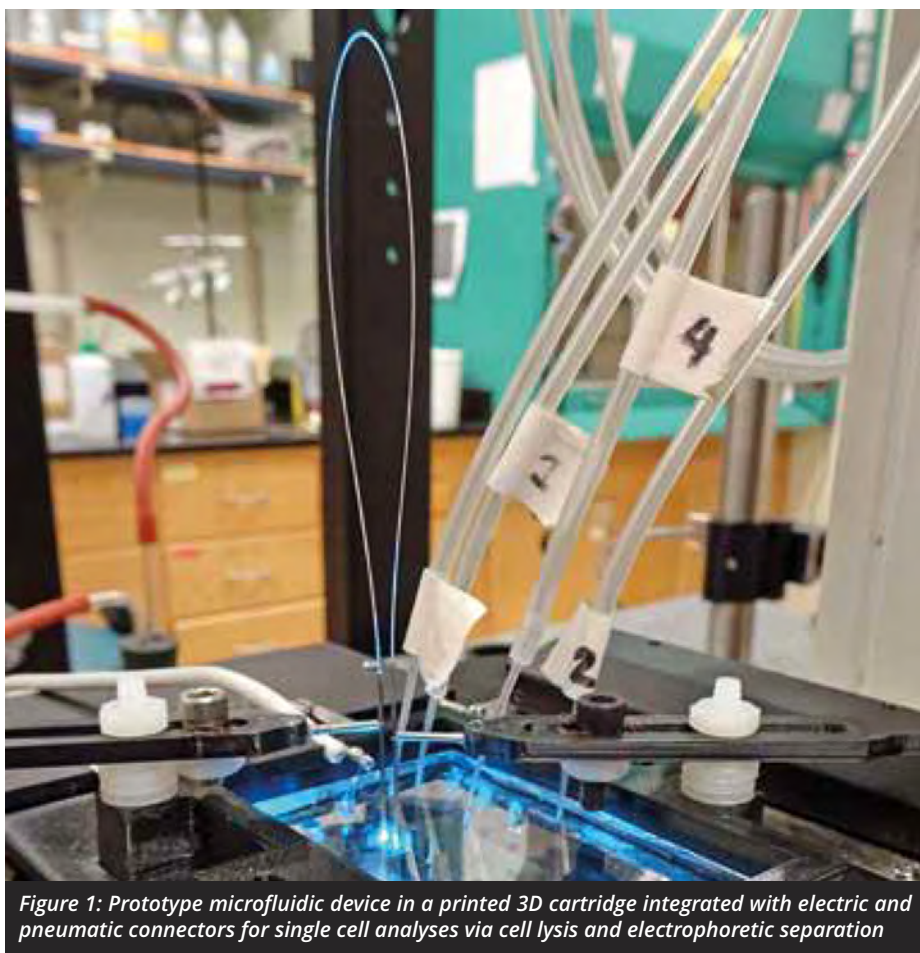
lab. Our technology will, for the first time, offer profiling in a timely manner so that it could be used for "point-of-care-devices" (POC) capable of:

- Detecting the onset of a disease (e.g. cancer in a group of risk patients (BRCA1,2 or other mutations) or asthma/chronic obstructive pulmonary disease (COPD));
- Detecting the progress versus regress of a disease during treatment (e.g. chemotherapy);
- Detecting the recurrence of a disease (e.g. solid tumours versus other inflammatory diseases) and;
- Precision pain management.

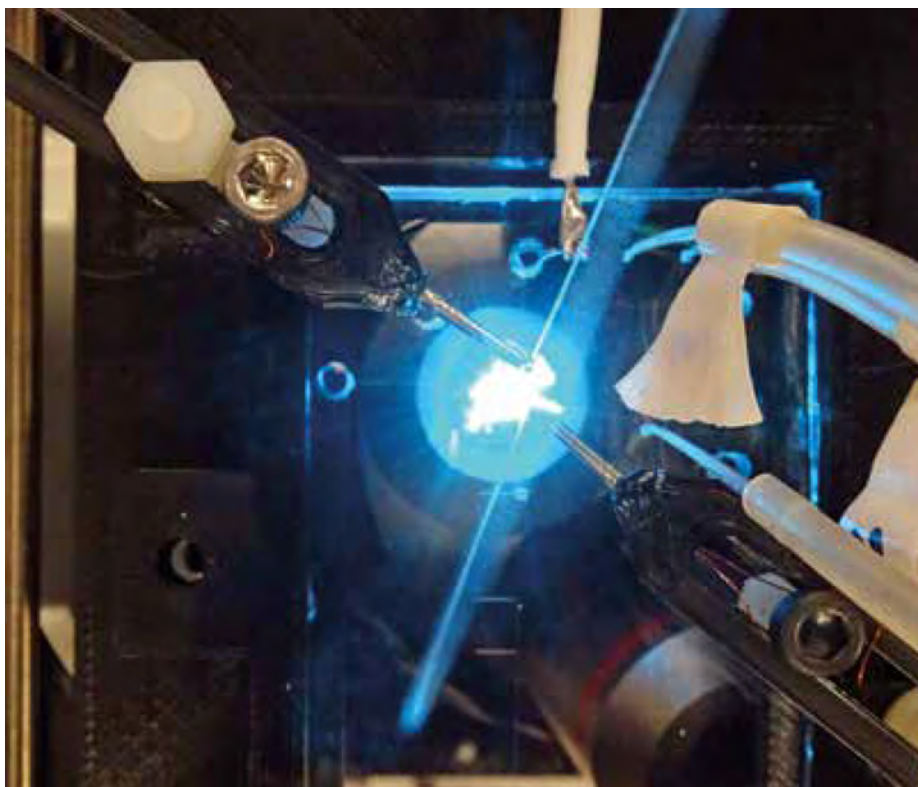
Our team is constantly designing new markers for reporting cell activities, such as key metabolic enzymes, proteolytic profiles, kinase network analysis and epigenetic reporting. Many of these markers are either designer peptides or contain designer peptides as functional elements.

## Seeing cells

Microfluidic devices are inherently well-suited to looking at biological processes, as the micrometre channel size conveniently corresponds to the size of cells. Most cells are between 1 – 100 micrometres, with a human hair being approximately 60 micrometres thick. This means that the channels can not only be used to provide a highly controlled environment for cell



*Figure 1: Prototype microfluidic device in a printed 3D cartridge integrated with electric and pneumatic connectors for single cell analyses via cell lysis and electrophoretic separation*



*Figure 2: Two 3-D printed micromanipulators are used to align the fibre with the microfluidic channels and the laser light emitted from a microscope objective*

growth, that is often more effective than a human-scale lab, but also to separate out different cells of different sizes.

We have already succeeded at using optical fibres to integrate this light detection technology onto a lab-on-a-chip. What is unique about our design and project is the off-chip placement of the optical fibre bridge: this means the chip design is not further complicated by the inclusion of the fibre. One of the big challenges with microfluidic devices is in their design; making components on such a small scale is difficult to do reliably and inexpensively, so this is a key advantage of our design.

Another unique feature of our project is creating a microfluidic device with multiple detection and excitation spots to detect the sample of interest, while still using only one laser and detector. The motivation behind this is to increase the versatility and capa-

bilities of the device. Now with the integration of the optical fibres, they can detect the intact cell before the breakdown of the cell membrane, as well as the components from the cell after it is lysed. Each of the excitation spots on the microchip is like a viewing window for the cell's activities, so the greater the number of spots you have, the greater the amount of information you can obtain. With more information, it becomes possible to better understand exactly how diseases lead to deformation and destruction of the cell.

## Counting lines

We want to go beyond just being able to image and identify cells. This work involves designing very bright markers, so when the cells bind a chemical marker that glows after it absorbs light from a laser, this emitted light from the cell is sufficiently intense that a single molecule in a single cell can be detected. These markers also have to be rapidly taken up by the cell

so that the detection can be done in 'real time'. This is important if this device will be used to reduce patient diagnosis times. This will be achieved by combining ultrabright fluorescent dyes or quantum dots with state-of-the-art peptide design, which enables the uptake and transport of markers to cellular targets (e.g. mitochondria or nucleus) within minutes. A large number of enzyme markers that can be monitored will allow for the detection of many possible diseases.

The work combining optical fibres with microfluidic devices will open up many new possibilities in understanding diseases at the cellular level and more tools for cell imaging and diagnosis. All of this is an important part in the development of lab-on-a-chip technology for making rapid, hand-held diagnostic devices a routine part of healthcare.

## KANSAS STATE UNIVERSITY

**Prof Dr Stefan H. Bossmann**  
**University Distinguished Professor**  
 Kansas State University  
 Tel: +1 785 532 6817  
[sbossman@ksu.edu](mailto:sbossman@ksu.edu)  
[www.k-state.edu/chem/people/grad-faculty/bossmann/MicrofluidicWelcome.html](http://www.k-state.edu/chem/people/grad-faculty/bossmann/MicrofluidicWelcome.html)  
[www.twitter.com/BossmannDr](https://twitter.com/BossmannDr)

**Prof Dr Christopher T. Culbertson**  
**Associate Dean for Research**  
 College of Arts & Sciences  
 Department of Chemistry  
 311 King Hall  
 Manhattan, KS 66506  
[culbert@ksu.edu](mailto:culbert@ksu.edu)  
 Tel: +1 785 532 6685

# Chemistry for the future of Europe

Alex Schiphorst, Science Communication and Policy Officer discusses the vital role of chemistry when it comes to the future of Europe

A significant part of European heritage and history lies in its rich history of pioneering discoveries and research in science and in the field of chemistry. Over the centuries, European chemists developed practices and theories, as well as vast networks of collaboration between themselves, between institutions and between countries. This central science was soon understood to have implications far and wide, ultimately impacting everything around us. Europe today continues to remain a leader in knowledge creation across an extensive range of research areas.

More recently, the United States, together with China and Japan have become scientific powerhouses with ambitious visions for the future of research and innovation. [EU statistics show](#) that the gross domestic expenditure on research and development in the EU in 2015 was 2.04%, just below China's 2.07%, but lagging behind the U.S.'s 2.79% and Japan's 3.29% – let alone South Korea's 4.22%. The EU's Europe 2020 strategy adopted in 2010 to aim for 3.00% of GDP for research and development by 2020 is unlikely to be achieved.

The failure to push forward on clear objectives and to strengthen Europe's budgets for scientific research and innovation is not without consequences and although Europe continues to be a leading centre of expertise and knowledge in many fields, it is being outdone by increasingly stiff competition.

It is in such a context that EuChemS, the European Chemical Society – an umbrella organisation representing national chemical societies and by extension over 150,000 scientists – was glad to see a new level of ambition and vision expressed by the European Commission and the European Parliament in their proposals for the next EU research framework programme, Horizon Europe. The political agreement reached between

negotiators for the European Parliament and national governments on Horizon Europe was met by an overwhelming vote in favour by the European Parliament. The move sends a strong signal to the negotiators of the next EU budget of the importance of science, research and innovation in the future of Europe.

The European Commission's proposal for a €100 billion budget, followed by the European Parliament's wish for a €120 billion budget, would in effect make this the biggest research and innovation programme ever in the EU – but it is a figure that still falls short of the €180 billion advocated for by most science and research institutions and organisations, universities and researchers. The future of the budget is not entirely clear, however, and it is with the next European Parliament that the negotiations will be conducted.

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**“For quality science, ample opportunities for researchers and greater innovation, the right policy framework that encourages scientific discovery and experimentation is needed. The scientific strength of Europe also lies in cooperation between scientists from different countries, each of them demonstrating quality expertise in their various research fields.”**

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The chemical sciences play a central role in helping develop answers to a wide range of issues, whether related to health, the environment, climate, energy, agriculture, food safety and beyond. The proposal for 'Missions' within Horizon Europe (high-profile initiatives intended to have a transformative impact on challenges European citizens face) was a welcome novelty. Five mission themes have already been agreed between the European Parliament and the Council, including targets to fight cancer, adapting to climate change, healthy oceans, seas, coastal and inland waters, smart, climate-neutral cities and soil health and



food. The chemical sciences will have an important part to play, being an essential part of most research within these fields.

Through focused workshops, EuChemS has aimed to demonstrate the concrete role the chemical sciences can play in providing advice and support to policymakers. By bringing together representatives from the European institutions with scientists and stakeholders, we offer a platform on which views can be successfully shared and discussed.

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**“The failure to push forward on clear objectives and to strengthen Europe’s budgets for scientific research and innovation is not without consequences and although Europe continues to be a leading centre of expertise and knowledge in many fields, it is being outdone by increasingly stiff competition.”**

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Recent workshops have included a look into the contentious debate over the potential risks of glyphosate, as well as the latest innovative measures aimed at providing a cure for Parkinson’s disease. A workshop held in March this year spotlighted the employability of chemists and the need to better enhance support and network-building between academia and industry. The message will strongly resonate with Horizon Europe’s foreseen partnerships.

For quality science, ample opportunities for researchers and greater innovation, the right policy framework that encourages scientific discovery and experimentation is needed. The scientific strength of Europe also lies in cooperation between scientists from different countries, each of them demonstrating quality expertise in their various research fields. Together, European countries can successfully compete with the research and innovation capacity of such countries as the United States or China. One of the major assets of EU research framework programmes in the past has been the opportunity for non-EU countries to take part. In view of the looming departure of the United Kingdom from the EU, EuChemS is concerned that few details have so far emerged on the status that will be given to the UK, as well as other third countries in the Horizon Europe programme. Recent findings demonstrate that greater

collaboration between countries results in more impactful and quality scientific output. At stake is also the mobility of Europe’s researchers – who increasingly rely on the ability to meet their peers, travel to conferences, work in collaborative projects.

As Horizon Europe takes shape, EuChemS has also contributed to the debate on another major change currently rocking the scientific world, namely, the move towards open science and open access publishing. The field of chemistry will be strongly transformed by such processes. But the transition to open access, also a core tenet of Horizon Europe, needs to be carefully approached. The consequences of a rushed transition, or one that does not take into account the global landscape could harm European science. EuChemS has, through a Position Paper, strongly encouraged stakeholder cooperation and highlighted the vital role played by learned societies in shaping scientific knowledge production.

For chemistry and science to thrive, policymakers need to ensure that the correct policy framework is put into place, that adequate budgets are planned and that mobility and collaboration across borders are encouraged. Horizon Europe has the potential to significantly alter the current state of research and innovation in Europe – but ambition and resolve will be essential. ■

**Alex Schiphorst**  
**Science Communication and Policy Officer**

The European Chemical Society (EuChemS)

Tel: +32 (0)2 289 25 67

secretariat@euchems.eu

www.euchems.eu

www.twitter.com/EuChemS

# Sustainable fuels: Characterisation of intermetallic alloy catalysts for decentralised methanol production

Efficient and decentralised production of sustainable fuels for today's transport infrastructure is discussed here by the Technical University of Denmark, who call for the development of highly active catalysts

Society needs alternative energy production systems. Sustainable synthesis of fuels in decentralised units constitutes a cheap, effective and stable solution, meeting needs from industry and users. Methanol ( $\text{CH}_3\text{OH}$ ) is a highly used chemical with a large variety of applications. <sup>[1]</sup> Furthermore, it has been suggested to use methanol as transportation fuel <sup>[2]</sup> as an alternative to conventional petroleum-based fuels. Industrial scale synthesis of methanol from syngas is typically carried out at elevated temperatures and pressures over a  $\text{Cu/ZnO/Al}_2\text{O}_3$  catalyst between 200-300°C and 50-100 bar. <sup>[3]</sup> This pressure level is relevant for industrial applications, but such processes involve large scale production units, high operational and investment costs. Decentralised units would constitute cheap and mobile facilities that produce liquid fuel (methanol) from solar- or wind-generated hydrogen. A catalyst suitable for such a decentralised application requires different conditions compared to known catalysis of methanol synthesis. If methanol has to be produced in decentralised units, a low temperature and pressure process needs to be developed. A schematic presentation of this dream scenario is illustrated in Figure 1. <sup>[4]</sup>

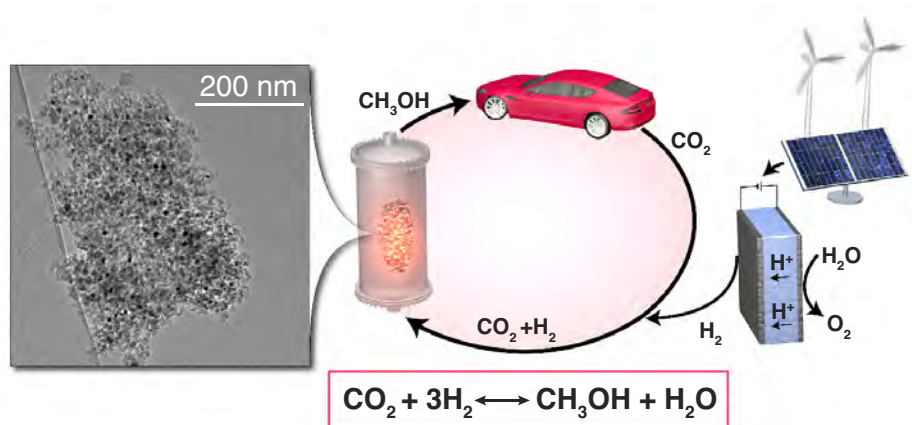


Figure 1: Carbon dioxide and hydrogen from electrolysis of water are converted catalytically into methanol at low pressure and temperature over. Image credit Jakob Kibsgaard.

In a collaboration between the Villum Center for the Science of Sustainable Fuels and Chemicals at DTU and the electron microscopy facility at Nanolab DTU, several bi-metallic intermetallic alloy catalysts have been studied and found highly active for ambient pressure methanol production directly from  $\text{CO}_2$  and  $\text{H}_2$ . By employing *in situ* high-resolution electron microscopy (HRTEM) and x-ray based methods, such as absorption spectroscopy (XAS) and diffraction (XRD), an important understanding regarding the correlation between the catalytic activity and the catalyst elemental composition and structure has been obtained. This

knowledge is essential to further optimise and develop novel catalysts for sustainable methanol production.

During the synthesis of methanol from  $\text{CO}_2$  and  $\text{H}_2$ , several competing reactions can occur. The most devastating is the reverse water gas shift (rWGS) reaction, where  $\text{CO}$  and  $\text{H}_2\text{O}$  are formed and methanation, where  $\text{CH}_4$  and  $\text{H}_2\text{O}$  are formed. In both cases, the formed  $\text{H}_2\text{O}$  pushes the methanol equilibrium towards the reactants and, thus, lower the overall methanol yield. Furthermore,  $\text{CH}_4$  and  $\text{CO}$  can deactivate the catalyst through restructuring or carbon poisoning

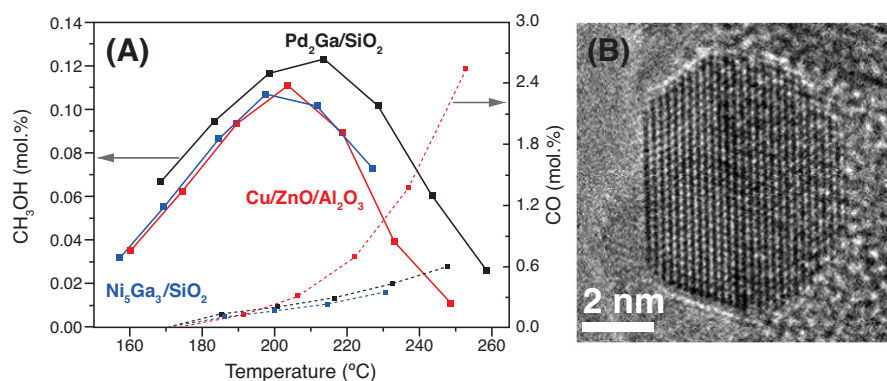


Figure 2 (A) Methanol and CO yield vs. temperature for Cu/ZnO/Al<sub>2</sub>O<sub>3</sub>, Ni<sub>5</sub>Ga<sub>3</sub>/SiO<sub>2</sub> and Pd<sub>2</sub>Ga/SiO<sub>2</sub>, respectively. (B) HRTEM micrograph of a single Ni<sub>5</sub>Ga<sub>3</sub> nanoparticle acquired at 700°C in 1mbar H<sub>2</sub>.

through dissociation. Thus, the overarching goal has been to find highly selective catalysts i.e. a catalyst that works efficiently for the methanol reaction and prohibits competing reactions.

This is the case for Pd<sub>2</sub>Ga<sup>[5,6]</sup> and Ni<sub>5</sub>Ga<sub>3</sub><sup>[7,8]</sup> catalysts, which has been found by Fiordaliso et al. and Studt et al. and Sharafutdinov et al., respectively, to be as active or more active than Cu/ZnO/Al<sub>2</sub>O<sub>3</sub> catalyst. Figure 2 (A) illustrates the methanol and CO yield vs. temperature for all three catalytic systems. Both Pd<sub>2</sub>Ga and Ni<sub>5</sub>Ga<sub>3</sub> produces less CO than the conventional Cu/ZnO/Al<sub>2</sub>O<sub>3</sub> at temperatures above 200°C.

In order to, fully understand the structure-activity relationship, complementary characterisation methods were employed during both catalyst formation and catalytic tests. *In situ* XRD and XAS were used to follow the catalyst's average structural and electronic changes during synthesis and reaction conditions.<sup>[9]</sup> Nanoscale imaging and spectroscopy of catalysts in a gaseous environment were performed in an environmental transmission electron

microscope (ETEM). As an example Figure 2 (B) shows a high-resolution electron microscopy (HRTEM) micrograph of a single nanoparticle acquired during alloy formation at 700°C in 1 mbar H<sub>2</sub>. From HRTEM nanoparticle shape and size as well as crystallinity and exposed facets can be related to the catalytic activity, as well as ensemble averaging characterisation methods such as XRD and XAS.

The approach of combining complementary characterisation tools with catalytic test has proved to be a comprehensive and powerful method for studying intermetallic catalysts for CO<sub>2</sub> hydrogenation to methanol. Furthermore, the developed methodology would be applicable to a wide range of catalytic systems.

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**Christian Danvad Damsgaard**  
Associate Professor

DTU Nanolab/DTU Physics,  
Technical University of Denmark  
Tel: 45 4525 6487  
cdda@dtu.dk  
www.nanolab.dtu.dk  
www.fysik.dtu.dk

**Professor Jakob Birkedal Wagner**  
Head of Nanocharacterization Section

DTU Nanolab,  
Technical University of Denmark  
Tel: +45 4525 6471  
jakob.wagner@cen.dtu.dk  
www.nanolab.dtu.dk



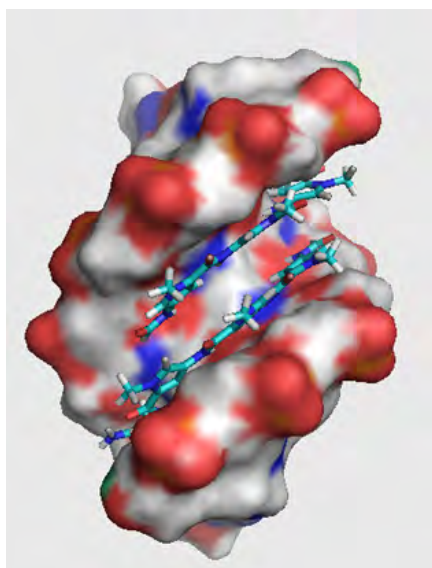
# Making chemistry matter: The value of discovery

Prof Colin J Suckling OBE DSc FRSE from the Department of Pure & Applied Chemistry, at University of Strathclyde, explains the value of discovery when it comes to making chemistry matter

In the previous issue of Open Access Government, I wrote about our scientific philosophy at Strathclyde and the value of combining research in medicinal chemistry with chemical biology. These continue apace but equally important at the University of Strathclyde whose defining strap-line is 'A place of useful learning and for the good of mankind', which is the translation of discoveries into products that do worthwhile things, in other words, development and commercialisation. Firstly before I turn to commercialisation, what are the potentially useful outcomes of our research awaiting development?

Our primary focus has been anti-infective compounds responding to the global need for new medicines to combat antimicrobial resistance in all its forms. The approach uses compounds that bind to DNA, so-called minor groove binders and those discovered at Strathclyde are referred to as S-MGBs. We have tackled bacterial, fungal and parasitic infection with some success taking individual S-MGBs forward as far as experiments in animal models of disease that demonstrate their ability to cure or reduce the impact of infectious disease, so-called proof of concept experiments.

By far the most advanced is an S-MGB for the treatment of *Clostridium difficile* associated diarrhoea being developed by our partner company, MGB



*A representation of S-MGBs (sticks) bound to the minor groove of DNA (solid)*

Biopharma and has now reached the stage of a Phase 2a clinical trial. This, however, is the only S-MGB currently in the clinical commercial domain. On the other hand, many others have successfully demonstrated proof of concept in relevant animal models of disease. With respect to parasites, four compounds have been found to be able to cure trypanosome infections in mice through experiments carried out at the University of Glasgow in Mike Barrett's laboratories and the University of Dundee in Kevin Read's laboratories. This means that we are now at the stage of selecting candidate compounds and preparing for preclinical studies.

It would be a mistake to think that we are only concerned with infectious

diseases in the developed world. The antitrypanosome project's focus is Animal African Trypanosomiasis (AAT) and aims to help some of the poorest farmers in the world to have healthy cattle herds. There are other significant international extensions too. Working with Ariel Silber at the University of Sao Paulo, Brazil, it has been found that one of our best antitrypanosomal compounds is effective against the South American species of parasite, *T. cruzi*, that is responsible for Chagas disease. In addition, we have a new collaborative project with the National Chemical Laboratory, Pune, India looking at the activity of our S-MGBs against the related parasite, *Leishmania*, which still causes widespread distressing disease in rural India.

S-MGBs are also effective with anti-fungal activity against *Aspergillus* spp. and *Candida* spp. as shown by studies with Mike Bromley of the University of Manchester. And most strikingly, we have recently learned from our collaborator Reto Guler at the University of Cape Town, South Africa, that two of our S-MGBs are effective at reducing the bacterial burden in a mouse model of tuberculosis without causing toxic or tissue-damaging effects to the animals. Very recently, we opened up the possibility of treating bacterial bovine mastitis with S-MGBs in partnership with the Veterinary School of the University of Glasgow.



*Colin Suckling in his office at the University of Strathclyde*

There are, nevertheless, some important gaps; high anti-Gram negative bacterial activity is still a problem for S-MGBs but our current discovery projects are beginning to break into this field too. A portfolio of such active compounds in such important fields from one academic chemical laboratory working with expert and resourceful biological partners around the world is a remarkable asset and has led to many significant academic publications. The challenge now is to go further and to bring these S-MGB discoveries into development so that they can be a benefit to people and animals in the clinic.

Turning now to development and commercialisation, if we did not live in a world in which we have to pay for what we do, we could develop without commercialisation. But that's eutopian. So one way or another we have to find a way for development to lead to distribution and some sort of market. As mentioned above, one S-MGB has already been developed by our partner company, MGB Biopharma, who have set up a current Phase 2 clinical trial

for *Clostridium difficile* associated diarrhoea (CDAD). GalvMED (Global Alliance for livestock and veterinary medicine) has contributed to the costs of the AAT project along with BBSRC. This, however, is the only direct industrial involvement so far.

It is well known that big Pharma has been reluctant to invest in anti-infectives both because of the scientific challenge and the commercial problem of recovering investment and, bluntly put, making a profit. As academic scientists, we can't do a great deal about this. We've fulfilled our responsibilities by creating a very extensive collection of anti-infective compounds and validating their potential in animal models of disease. That's just about as far as an academic group can go with academic funding. But we don't want things to stop here; we want to see our compounds out there in action in the clinic or in the field.

Translational funding has always been difficult to manage and the difficulties are multiplied with so many active

compounds to treat a wide range of serious infectious diseases. Moreover the unconventional target and mechanism of action of S-MGBs, with respect to industry norms, leads to great caution on behalf of commercial funders, the fact that one of our early compounds has reached a Phase 2 clinical trial notwithstanding. Our experiments also show that S-MGBs are also very resilient to the development of resistant strains. They are, therefore, very much compounds for the antimicrobial resistance era. Much public and political rhetoric has been expended on the crisis of antimicrobial resistance. In the S-MGBs, we have a class of compounds that can make a real contribution to mitigating the crisis in many fields of infection. Our search, not so much for compounds now, but for translational funding continues.



**Prof Colin J Suckling OBE DSc FRSE**  
**Research Professor of Chemistry**  
 Department of Pure & Applied Chemistry,  
 University of Strathclyde  
 Tel: +44 (0)141 548 2271  
[www.strath.ac.uk/chemistry/](http://www.strath.ac.uk/chemistry/)

# Cutting-edge life sciences and technologies: Assessing chemicals exposure toxicity

Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group explains cutting-edge life sciences and technologies that assess exposure toxicity when it comes to chemicals, including novel tools to address human health and environment

The increasing interest shared by government authorities, industries and the public, on sustainable environmental quality demonstrated by most countries aligned with the United Nations Sustainable Development Goals during the past five years has led to important discussions about the concentration of chemicals used in cities, mostly focused on the emerging risks to public health and environment risks. As a consequence, a new perspective regarding global environmental assessment and management activities are critically needed (Brooks, 2019), including a solid integration of green chemistry with ecotoxicology, that tends to moderate the exposure of citizens to hazardous substances.

It is relevant to highlight the role of the global market of chemicals and its huge impact on employment and economic growth. However, when inappropriately discharged in the environment these chemicals become environmental pollutants with the potential to generate a broad spectrum of acute and long-term side effects over human health, mostly affecting the endocrine function and the immune system.

Regional frameworks for standardised environmental risk assessment propose systematic processed for assessing the probability that adverse effects may occur as the result of exposure to chemicals in the environment (Sanchez and Egea, 2018). Overall, procedures begin with a strong formulation of a problem statement; the evaluation of the apparent routes, along with a study taking into account severity, duration and frequency of exposure; the prediction of the adverse or toxic effects; and ultimate risk characterisation. Nevertheless, the availability of data and/or models for estimating exposure and probable effects may significantly influence quality risk evaluations,

therefore, notably affecting environmental safety decisions.

## Opportunities and solutions

During the past two years, health and environmental researchers have started to focus on the use of predictive, high-throughput screening (HTS) assays to characterise the capability of chemicals of influencing biological pathways and its potential to produce adverse side effects on human and ecosystems health (Villeneuve et al., 2019). Indeed, HTS assays can be easily automated and speedily carried out run in 96-, 384-, or 1536-well plate formats with the purpose to measure the effect of a myriad of substances over a wide concentration range on a particular biological process.

Moreover, HTS assays can be enriched with additional chemical-specific information depicting the physico-chemical properties of a substance, structural features, functional groups, etc., to categorise potential exposures and critical aspects to take into consideration associated with the uptake and metabolism. Additionally, an in-depth understanding of the underlying biological pathways may significantly enhance quantitative predictive modelling and simulation.

Additionally, other kinds of assays can be performed around long non-coding ribonucleic acid (lncRNA), a class of RNA exhibiting more than 200 nucleotides and lacking protein-coding potential. These molecules have demonstrated to take place in a broad range of physiological and pathological processes, as epigenetic factors. Therefore, lncRNAs constitutes a promising tool to assess the response of organisms to environmental stress, especially toxicity assays. Indeed, modified expression profiles of lncRNAs have been categorised





*Algal Bloom or Algae Bloom, produced by man made chemicals, is believed to contribute to global warming*

to establish a series of patterns that allows evaluating health and ecosystem health status (Huang et al., 2018).

### Final remarks

The scientific community is heavily committed to attenuate the effects of environmental pollutants and the emerging compounds in human health and environment. Beyond regional frameworks and standardised procedures, novel cutting-edge life sciences technologies are starting to play a significant role in the high throughput screening of chemicals and the subsequent evaluation of their effects on the whole ecosystem.

Stronger relationships between industry and research in toxicology and ecotoxicology in order to promote the advent of green technologies and circular economy are critically required to address present and future concerns around climate change and biodiversity decline. ■

#### Acknowledgements

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**Cecilia Van Cauwenberghe, PhD, MSc, BA**  
**Associate Fellow and Senior Industry Analyst**

TechVision Group, Frost & Sullivan  
 cecilia.vancauwenberghe@frost.com  
 ww2.frost.com  
 www.twitter.com/Frost\_Sullivan

# Climate toxicology: The impact on human health

Eduardo A. González, B.S. and Pamela J. Lein, Ph.D., University of California, Davis discuss how global climate change is increasing toxicological impacts on human health

The global climate is changing at an unprecedented pace, driven largely by increased carbon dioxide emissions that are steadily warming the Earth. Worldwide warming trends are contributing to melting of the polar ice caps, rising sea levels, worsening global air pollution, deteriorating watershed conditions, drought, and increased frequency and severity of extreme weather events. As documented in the 2018 World Health Organization (WHO) COP24 Special Report entitled “Health & Climate Change”, these destabilising climate changes are already exerting significant negative impacts on human health.

Direct effects of climate change on human health include the physiological effects of extreme heat (heatstroke and increased incidence of heart attacks, stroke and respiratory distress), as well injuries and death caused by extreme weather events, such as drought, floods, heatwaves, storms and wildfires. Climate change also affects human health indirectly, largely via ecological changes that compromise food and water security, promote the spread of infectious disease, and/or force the displacement of populations. Emerging scientific evidence suggests that global climate change also impacts human health by increasing human exposure to toxic chemicals and/or increasing chemical toxicity.

A number of persistent organic



pollutants have historically been sequestered in polar regions due to the phenomenon of global distillation. Temperature and wind patterns carry volatile chemicals towards the poles, depositing them in frozen water and soils for decades.

However, melting of the polar ice caps is releasing these pollutants back into the environment. Multiple studies have documented increasing levels of bisphenol A, polychlorinated biphenyls, and DDT, being released from polar regions. Increasing temperatures allow these chemicals to more readily transition into the gaseous phase, which facilitates their global redistribution.

Current climate prediction models estimate significantly altered patterns

of precipitation, and significantly increased incidence of extreme weather events. Increased rainfall will increase chemical deposition into soils and runoff into water sources. Increased nutrient runoff due to flooding or increased irrigation in areas of drought coupled with warming of surface waters will increase the incidence, geographic distribution and duration of harmful algal blooms. Human exposure to algal toxins via ingestion of contaminated seafood, skin contact with affected waters, or inhalation of toxins that have become airborne is linked to nausea, vomiting, diarrhoea, paralysis, slurred speech, and other neurological symptoms.

Conversely, in areas experiencing decreased rainfall, air pollutants will persist longer in the atmosphere.

Drought will increase the likelihood and magnitude of dust storms. Both of these scenarios can increase human exposure to pollutants via inhalation. Decreased rainfall is also linked to a predicted tripling in the incidence of wildfires by 2050.

**“Global climate change is the greatest health challenge of the 21st century. The health impacts of climate change are predicted to force 100 million people into poverty by 2030, with significant impacts on mortality and morbidity.”**

Exposure to the smoke generated by wildfires, as well as the toxic chemicals generated by pyrolysis that remain in the debris, pose significant risks for human health. The most toxic components of wildfire smoke include carbon monoxide and particulate matter, which exacerbate cardiorespiratory disease and adversely impact brain function, whereas wildfire debris often contains elevated levels of toxic metals and persistent organic pollutants.

Climate change is predicted to increase human exposures to pesticides. For example, warming temperatures will likely shift agricultural zones towards higher latitudes. This change will be accompanied by increased application of pesticides in areas where pesticide usage has traditionally not been heavy. A warming climate is also expected to expand the geographic range of mosquitos and other disease-carrying insects over the next 30 years.

Many nations are facing or will be faced with the challenge of managing malaria or other infectious diseases carried by mosquitos, which likely result in expanded use of dichlorodiphenyl-trichloroethane (DDT). DDT, a persis-

tent organochlorine insecticide, has been linked to increased risk of obesity and metabolic disorders, cardiovascular disease, and cancer. In addition to increasing human exposure to toxic chemicals, global climate change is predicted to exacerbate human response to toxic chemicals.

For example, warmer temperatures have been shown to increase the toxicity of some metals, including lead and cadmium, on wildlife health, and data suggests that this may be the case for humans as well. A similar relationship is reported for pesticides and air pollution: the negative effects of these toxic chemicals on the heart, lungs, and brain are exacerbated by increasing temperature.

The biological basis for this relationship is unknown, but a leading hypothesis is that increasing body temperature increases the activity of enzymes involved in the metabolism of toxic chemicals, some of which detoxify the chemical, but many of which increase chemical toxicity. An alternative explanation derives from experimental and epidemiological studies indicating that chronic stress exacerbates the effect of toxic chemicals. There is abundant evidence indicating that global climate change increases stress, particularly in those populations facing food or water insecurity or who have been displaced by climate-driven events.

Another mechanism by which global climate change increases chemical toxicity is the depletion of the ozone layer, which filters out harmful ultraviolet (UV) radiation. Increased UV levels at the Earth's surface increases the toxicity of phototoxic chemicals, defined as chemicals that have increased toxicity with exposure

to UV radiation. Phototoxic chemicals include titanium dioxide nanoparticles, a common ingredient in sunscreen, medicine, and toothpaste.

Global climate change is the greatest health challenge of the 21st century. The health impacts of climate change are predicted to force 100 million people into poverty by 2030, with significant impacts on mortality and morbidity. A highly conservative estimate of 250,000 additional deaths each year due to climate change has been projected between 2030 and 2050. These estimates did not take into account the impacts of climate change on the toxicological impacts on human health, so the true impacts could be even greater. Collectively, these data underscore the significance of the conclusion reached by WHO that the global costs of mitigating climate change would be more than offset by the savings in human healthcare costs.



**UC DAVIS**  
VETERINARY MEDICINE

**Eduardo González**  
Ph.D. Graduate Student  
University of California, Davis  
azgonzalez@ucdavis.edu  
<http://www.vetmed.ucdavis.edu/lein-lab/>

**Pamela J. Lein**  
Professor  
University of California, Davis  
Tel: +1 530 752 1970  
pjlein@ucdavis.edu  
<http://www.vetmed.ucdavis.edu/lein-lab/>  
[www.twitter.com/UCDATEHS1](https://twitter.com/UCDATEHS1)



# Combining a bottom-up movement: Endocrine disruptors and non-communicable diseases in Africa

Chiara Frazzoli and Alberto Mantovani from Istituto Superiore di Sanità share their insights into endocrine disruptors and non-communicable diseases in Africa in terms of combining a bottom-up movement in collaboration with NOODLES Alliance Network

In Africa, the burden of diseases indicates a new era of comorbidities, in regards to risk factors, as well as clinical features, from chronic multifactorial diseases to multi-diseases or “altered functionalities”. High (and uncontrolled) rates of toxic exposures are due to lack of awareness and governance and immature or non-existent legislation and infrastructures; widespread exposures change along with lifestyles, the living environment, food production and global market of consumers’ products, including dumping. Concerning pesticides, biocides, flame retardants, food contact materials: the overall daily burden of new toxicants in the African scenario might exceed the body protective detoxification rate and the whole ability of the body to restore a functional internal environment. Global sustainable development pivots on ethics in global informal (for instance, e-waste) and formal market (for example, bisphenol A-containing baby bottles). Along with this, African proactiveness on healthier environments will stem on both increased knowledge and stronger awareness.

In growth-eager societies, risk reduction measures may meet resistance due to the short-term loss of some economic benefits, but unhealthy economic growth may trigger the

onset of serious health problems later on or to the next generation. Globally, increased knowledge on long-term or transgenerational effects including endocrine disruption, calls for up-to-date, often stricter policies, with banning of several seemingly “useful” substances, for example, the recent inclusion of perfluorooctanoic acid in the Stockholm convention.

The driver of both health and economy is food: the potential wealth of Africa comes from within, from its land and primary food production. The enforcement of up-to-date safety rules on toxicants will facilitate the market access for African producers, both within Africa and in the rest of the world. Due to growing awareness in a number of countries (e.g. Algeria, Cameroon, Ghana, Nigeria, Senegal, South-Africa), safe food production is expected to rise in large parts of Africa. Both clean food chains (e.g. with science-driven, sustainable use of fertilisers, pesticides, veterinary drugs, sanitisers) and a re-established value chain (supported by e.g. control, certification and traceability) may provide young African enterprises with an impetus for new business opportunities; in particular, farmers would be recognised for their strategic role in supporting both community health and wealth.

Community strategies should develop a rural-urban integration, including the transfer of knowledge from, for instance, universities to farms. Mass media have a key role to play due to lack of consumer awareness; mass media communication can rapidly change the preferences and perception of products. African land is potentially rich in raw foods but local productions often provide poor access to the local and global markets and face heavy challenges from international brands which often are perceived as of higher quality. African countries, even those having well-rooted farming traditions, import low quality (but more affordable) products. For instance, in Mali, a country with a strong pastoral root, the use of imported condensed milk is widespread in urban communities, while efforts – however valuable – for exploiting traditional dairy products are still at an early stage.

In the African scenario, nutrition is the main factor for diseases prevention and health promotion. Chemical contaminants may interact with nutrition by exerting “antinutritional” effects. For instance, endocrine disruptors acting on thyroid, like perchlorate, may both interfere with iodine, thus inducing a nutritional deficiency and/or increasing the organism’ need for iodine. Other

pollutants, like dioxins or cadmium, may increase the requirements for nutrients (for example, selenium, vitamin E) involved in antioxidant defences.

**“Africa is the market of the future, as it represents 900 million consumers in need of and looking to all kinds of products. Global health thus requires the application of global ethics.”**

Also, endocrine disruptors can interfere with the action of hormones involved in energy metabolism (thyroid, insulin, adipokines, etc.) thereby acting as risk factors in the onset of “malnutrition-related” disorders, such as obesity and Type 2 diabetes. Indeed, nutritional imbalances may synergise with environmental and behavioural factors: some increasingly contaminated African environments also show the highest prevalence of essential chemical element deficiencies.

African countries are called to make critical choices for diseases prevention. Resources have to be devoted to relevant top-down (institution-driven) interventions, policies and programmes (for instance, national laws and regulations on imports and production, food control systems based on risk assessment and good quality laboratories). In parallel, rapid changes in global dynamics require mobilisation from the bottom-up. Waiting for improved regulations and their implementation, communities’ empowerment on good practices and responsible behaviours in daily life will support both informed choices, as well as avoiding or mitigating health risk factors.

In our view, science-supported bottom-up movement can mitigate avoidable toxicological health risk factors and help to develop responsive policies. This is the purpose of the sub-Saharan Africa NGO NOODLES

Alliance Network, where scientists and civil society are engaged in food safety, nutrition and related environmental aspects, with special attention given to risk factors for next generation’s health, such as endocrine disruptors. African scientific research on food and environmental toxicology, while still limited, is a growing reality which is well worth giving attention to. African scientists, therefore, have a key role in establishing the continuum between policy-makers, health practitioners and communities. Most African countries present data-poor scenarios but the scientific community working with society at large can build-up a fit-for-purpose risk analysis. In most cases, internationally accepted reference doses are available for hazard characterisation. A “diagnostic risk assessment” can then integrate the toxicological data in the local scenario to decide whether a problem calling for action does exist. When scientific data for risk assessment are either burdened by uncertainties or “insufficient”, precaution can be regarded both as a way to account for uncertainty and as a form of scientific solidarity.

In its turn, the bottom-up engagement of local communities may integrate and stimulate scientific research on food safety, as well as provide “unconventional” data sources. Interestingly, a bottom-up movement of scientists and citizens in a situation where high uncertainties exist but timely decisions are required appears close to the framework of “Post-Normal Science”.

Value choices unavoidably enter into the process of risk assessment. Evolution beyond “traditional” cultures must not be perceived as negative: however, changes must be understood. The new social trends shift towards later marriage, later first birth

and desire to have fewer children, with the biocultural adaptation that requires increased infants’ survival and protection of their healthy adulthood. Basing on the ONU view of “sustainability” the concept of Sustainable Food Safety can be defined as: “the complex of actions intended to avoid adverse health impact on the next generation associated to today’s safety of foods and nutritional quality of diet”. A sort of intergenerational negotiation should weigh the interests of current and future (to date non-represented) lives. Global trade takes part in such a negotiation. More developed countries should guarantee ethical trade: products posing significant health or environmental concern should not be exported to any country. Indeed, globalisation is changing the way we look at Africa. As nowadays recognised, Africa is the market of the future, as it represents 900 million consumers in need of and looking to all kinds of products. Global health thus requires the application of global ethics.



**Chiara Frazzoli**  
**Alberto Mantovani**  
 Istituto Superiore di Sanità  
 chiara.frazzoli@iss.it  
 alberto.mantovani@iss.it

# Reading the warning signs: Research needed to address the crisis of maternal mortality

Dr Diana W. Bianchi, Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the U.S. National Institutes of Health, details the critical need for research to address maternal mortality

**M**avis Stephens, a mother and U.S. Army veteran, recounted her near-death experience giving birth. She shared her story at a recent maternal health forum sponsored by my institute, reminding the audience of how precarious pregnancy can be for women and their offspring.

“Pregnancy can be a rollercoaster ride,” Stephens said. “Before you get on a rollercoaster, there are signs that say, ‘You need to be this tall to ride. If you’re not, don’t ride.’ We need those signs for pregnancy.”

I agree.

Stephens, who is African American, was in her 20th week of pregnancy when she started to see signs of trouble. She mentioned to her doctor that she was having headaches and feeling dizzy. He suggested she stay off her feet and cut back on dietary salt. At 27 weeks, she had blurred vision and unbearable headaches and dizziness. Her doctor took her blood pressure and immediately sent her to the nearest hospital emergency room. Tests showed she was struggling with preeclampsia, a pregnancy-related high-blood pressure disorder. Within a day, she was fighting to stay alive. She had an emergency C-section, but her baby boy died within two days. Her story was a wake-up call that we all should heed.

The United States has one of the worst maternal death rates in the developed world. The U.S. Centers for Disease Control and Prevention (CDC) estimates that 700 women die each year as a result of pregnancy or delivery complications. Death rates are higher among

women of colour. Even celebrity status and wealth aren’t enough to insulate women from these pregnancy-related health threats, as tennis champion [Serena Williams](#) and singer/songwriter [Beyoncé](#) have recently shared. According to the CDC, black and American Indian/Alaska Native women are about three times more likely to die from a pregnancy-related cause than white women.

In addition, serious and life-threatening complications following pregnancy, called severe maternal morbidity, have been steadily increasing. CDC estimates that since 2014, [more than 50,000 U.S. women](#) have been affected by severe, unexpected complications from labour and delivery.

My institute, NICHD, was founded more than 50 years ago specifically to understand and improve maternal health and pregnancy outcomes. Our research led to the development of the first home pregnancy test in the 1970s and has made several contributions to [reducing maternal morbidity and mortality](#), but much more needs to be done.

Maternal deaths can result from a variety of causes: a pregnancy complication, a chain of medical events started by the pregnancy, worsening of an unrelated condition because of the pregnancy and other factors. Death may occur during pregnancy, childbirth, in the 48 hours immediately following childbirth or up to one year after the pregnancy ends. Complications that do not result in death may cause short- or long-term health problems or disability, which can deeply affect a woman’s quality of life. A full spectrum of research is





*Dr Diana W. Bianchi*

early April 2019 was an opportunity for women, such as Mavis Stephens, to share experiences with health care providers and advocates.

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**“The United States has one of the worst maternal death rates in the developed world. The U.S. Centers for Disease Control and Prevention (CDC) estimates that 700 women die each year as a result of pregnancy or delivery complications. Death rates are higher among women of colour.”**

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In the biomedical realm, an ongoing NICHD research project called [PregSource](#)<sup>®</sup> allows women to track their pregnancy experiences. This crowdsourcing project uses confidential questionnaires to gather data directly from pregnant women in hopes of informing future studies aimed at improving maternal and obstetric care. In addition, NICHD has invested more than \$60 million to develop novel technologies that help us better monitor the development of the placenta throughout pregnancy. Among other accomplishments, the [Human Placenta Project](#) has supported the design of a [handheld device](#) that monitors the flow of blood and oxygen between mother and fetus. This small device may one day be used by expectant women to detect early warning signs of complications and to seek care accordingly.

Any maternal death is one too many. It shouldn't happen in the United States or anywhere else. We know there are warning signs, like the ones Stephens experienced. Let's work together to figure out how to read those signs, intervene and make a difference for every expectant woman and her family. ■

needed to better understand the causes of these deaths and how to prevent them in the United States and around the world.

Some of NICHD's recent research has found that [taking low-dose aspirin](#) may prevent the onset of preeclampsia in high-risk women. NICHD-funded researchers have also found that vaginal birth after a prior C-section – commonly called VBAC – is [safe under certain situations](#) and leads to lower infection risk and faster recovery. An NICHD-supported network helped determine that a low-cost drug, called misoprostol, [prevents maternal haemorrhage](#) (extreme bleeding) after delivery. This treatment has saved many lives in the developing world.

However, there is still much to be accomplished not only to understand the biomedical causes of maternal mortality, but also to understand the full social and behavioural factors that contribute to these deaths. Recent NICHD workshops highlighted the need to identify [research gaps](#) in data collection, clinical obstetrical factors and health disparities, specifically [racial and ethnic inequalities](#), in the care of women before, during and after pregnancy. Our [Community Engagement Forum on Improving Maternal Health](#) in

### **Dr Diana W. Bianchi** **Director**

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Tel: +1 800 370 2943

[NICHDInformationResourceCenter@mail.nih.gov](mailto:NICHDInformationResourceCenter@mail.nih.gov)

[www.nichd.nih.gov](http://www.nichd.nih.gov)

[www.twitter.com/nichd\\_nih](https://twitter.com/nichd_nih)

# Vitamin D and preeclampsia research: Improving maternal and foetal health

Yuping Wang and David F. Lewis, from Louisiana State University Health Sciences Center – Shreveport, share with us their fascinating research on vitamin D and preeclampsia research, including a promising option in this vein to improve maternal and foetal health

**V**itamin D deficiency is a newly recognised risk factor for preeclampsia. Drs Yuping Wang and David F. Lewis at Louisiana State University Health Sciences Center in Shreveport (LSUHSC-Shreveport) are exploring ways of vitamin D to protect placental cells by targeting vitamin D receptor (VDR), a promising option to improve maternal and foetal health.

Preeclampsia, characterised with increased maternal blood pressure and the presence of proteinuria after 20 weeks of gestation, is a serious complication in human pregnancy. This pregnancy disorder is one of the leading causes of maternal and foetal morbidity and mortality worldwide. Although the cause of preeclampsia is not clear, recent studies have shown that low maternal vitamin D levels are associated with a higher incidence of preeclampsia. Therefore, it is considered that vitamin D deficiency is a risk factor for this pregnancy disorder. Since placental cell dysfunction plays significant roles in preeclampsia development, the research at LSUHSC-Shreveport aims to address the roles of vitamin D in placental cells (trophoblasts, foetal vessel smooth muscle cells (VSMCs) and endothelial cells) and to better understand how vitamin D, a pleiotropic hormone, could

ameliorate or rescue placental cell dysfunction in preeclampsia.

## Vitamin D metabolic system in placental cells

The key molecules that engage in synthesis and degradation of vitamin D include vitamin D binding protein (VDBP, that carries and delivers 25(OH)D and 1,25(OH)<sub>2</sub>D<sub>3</sub> to target cells and tissues), *25-hydroxylase* (converts cholecalciferol to calcidiol, 25(OH)D), *1 $\alpha$ -hydroxylase* (converts calcidiol to calcitriol, 1,25(OH)<sub>2</sub>D<sub>3</sub>), *24-hydroxylase* (degradates both 25(OH)D and 1,25(OH)<sub>2</sub>D<sub>3</sub>) and *vitamin D receptor* (VDR). 1,25(OH)<sub>2</sub>D<sub>3</sub> is the bioactive form of vitamin D. After binding to its receptor VDR and forming heterodimer with other nuclear hormone receptors, the complex then binds to vitamin D response elements (VDRE) in the promoter of genes, in which it regulates and subsequently elicits downstream vitamin D biological actions. Therefore, VDR is an absolute determinant of vitamin D bioactivity.

To study vitamin D metabolism in the human placenta, Drs Wang and Lewis team demonstrated that placental cells are enriched with all the elements that are involved in the synthesis and catabolism of vitamin D. Their results showed:

- 1) VDBP and VDR are strongly expressed in placental trophoblasts throughout pregnancy;
- 2) Vitamin D synthases (*25-hydroxylase* and *1 $\alpha$ -hydroxylase*) are not only in trophoblasts and VSMCs but also present in foetal vessel endothelial cells, especially in the third trimester/term placentas, while vitamin D catabolic enzyme (*24-hydroxylase*) is weakly expressed in placental cells throughout pregnancy and;
- 3) VDR expression is inducible by 1,25(OH)<sub>2</sub>D<sub>3</sub> in trophoblasts, VSMCs and foetal vessel endothelial cells. These findings indicate that placental cells could produce and store vitamin D to maintain its homeostasis within the placental microenvironment and to provide and transfer prehormone (25(OH)D) from the maternal circulation to the foetus to support the growing foetus' requirements.

Their works further demonstrated that in preeclamptic placentas, trophoblasts had altered levels of vitamin D synthesis and catabolic enzymes, along with a reduced amount of VDR. Their studies also demonstrated these changes seen in

trophoblasts could be induced by mimicking preeclamptic condition induced by oxidative stress in the laboratory.

## Could vitamin D improve placental cell function in preeclampsia?

It is known that not having enough vitamin D during pregnancy increases the risk of preeclampsia, but how vitamin D is able to affect placental cell function and whether vitamin D could reverse any of the alterations associated with placental cell dysfunction in preeclampsia are less clear. To answer the questions, the team took the approach to look into the most relevant adverse events that occur in placental trophoblasts in preeclampsia: increased oxidative stress and superoxide generation, increased vasoconstrictor thromboxane and inflammatory cytokine production and increased microparticle release.

Using primary trophoblasts from the human placenta, they demonstrated that bioactive vitamin D,  $1,25(\text{OH})_2\text{D}_3$  could suppress oxidative stress-induced increase in thromboxane production and superoxide generation, which is due to the ability of vitamin D to inhibit cyclooxygenase-2 (COX-2) upregulation since both thromboxane and superoxide are metabolites of cyclooxygenase pathway. They also demonstrated that  $1,25(\text{OH})_2\text{D}_3$  could suppress oxidative stress-induced microparticle release by placental trophoblasts via preservation of eNOS expression and inhibition of caspase-3 cleavage and ROCK1 activation in trophoblasts. These findings are important because thromboxane is a potent vasoconstrictor and suppression of thromboxane production could reduce vascular contractility and improve placental blood perfusion.

Moreover, suppression of microparticle release would diminish maternal vascular inflammatory response induced by trophoblasts-derived harmful stimuli. In addition, their data also show that  $1,25(\text{OH})_2\text{D}_3$  could inhibit inflammatory cytokine  $\text{TNF}\alpha$ , IL-6 and IL-8 production. Their work, combined with others of suppression of sFlt-1 production by vitamin D, holds a promise that vitamin D has the ability to improve and restore trophoblast function in preeclampsia.

In addition to trophoblasts, they also proved favourable effects of  $1,25(\text{OH})_2\text{D}_3$  on foetal vessel endothelial cells and found that bioactive vitamin D could promote superoxide dismutase (CuZn-SOD) expression, an essential antioxidant to dismutate superoxide radicals. Their recent study also revealed that  $1,25(\text{OH})_2\text{D}_3$  could stimulate endothelial cells to produce more miRNA-126, an endothelial specific miRNA that exerts anti-inflammatory activities to govern vascular integrity.

The team also studied vitamin D effects on placental VSMCs and found that  $1,25(\text{OH})_2\text{D}_3$  could inhibit angiotensin II-induced placental VSMC contraction. Similar to that of losartan, an angiotensin II receptor – 1 (AT-1) blocker, by inducing a signalling mechanism called phosphorylation of the myosin phosphatase target subunit 1 (MYPT1) pathway molecule. This is a key player involved in myosin light chain phosphatase (MLCP) activation that is essential for VSMC relaxation.

## Could VDR hold a key to improve trophoblast function in preeclampsia?

The actions of bioactive vitamin D are mediated by VDR, a ligand-activated transcriptional factor that functions to

control target gene expression. VDR expression is inducible in placental cells. Therefore, the amount and the activity of VDR present in placenta cells, especially in trophoblasts, are critical to determining the biological effects of  $1,25(\text{OH})_2\text{D}_3$  derived from the maternal circulation, as well as produced by trophoblasts. However, the amount of VDR on trophoblasts is reduced in preeclampsia. Lack of VDR expression causes trophoblasts unable to respond to  $1,25(\text{OH})_2\text{D}_3$  properly. Hence, one of the goals of the research projects of Drs Wang and Lewis research is to find a way to promote VDR production/expression and increase VDR activity in trophoblasts to correct and restore trophoblast function and subsequently, to reduce the incidence or severity of this pregnancy disorder.



**David F. Lewis, MD, FACOG, MBA**  
**Professor and Chairman**  
 dlewi1@lsuhsc.edu

**Yuping Wang, MD, PhD**  
**Professor**  
 ywang1@lsuhsc.edu

Department of Obstetrics and Gynecology  
 Louisiana State University Health Sciences  
 Center – Shreveport  
 Tel: +1 (318) 675 5379



# Whole genome sequencing: It's getting personal

Professors Darren K Griffin and Alan R Thornhill discuss their research on exploring a person's genome sequencing

'Everybody is identical in their secret unspoken belief that way deep down they are different from everyone else' [David Foster Wallace].

This may well be true from a genomic point of view. Most of us know that we are comprised of cells, trillions of them, and within each nucleus of each cell is DNA, and the DNA encodes our genome.

Our genome is many things: It is the sum total of all our genes, it codes for the proteins that drive the chemical reactions in our bodies and the structures that keep us upright. It is the blueprint that sketches out aspects of our appearance, our health and our behaviour; it contains shadows of our evolutionary past. There are also many things that our genome is not. It is neither an un-editable script for our life, nor is it a list of pre-determined events that set us on a specific path. Like any blueprint, it is no more than an outline, a plan for what might be.

But what happens when our genome is sequenced? How do we interpret this overwhelming mass of information and the implications for our health, wellbeing and identity?

Many countries have launched large studies to investigate genome sequencing. In the UK, the 100,000 genomes project aims to better



*Dr Helen O'Neill from UCL. By choosing to have her genome sequenced, simultaneously she received information about her identical twin sister. One of her key findings was to discover that she was a low metabolizer of the commonly prescribed pain-relief medication codeine. Following a bad car accident her dose was doubled when she complained that it wasn't working. Such findings, she says, would have massive implications for how drugs are prescribed and could avoid a great deal of unnecessary suffering and provide much-needed savings for a cash-strapped NHS service.*

understand the genetic basis of specific conditions including cancer, cardiac and rare disease by comparing whole genomes from large numbers of people. This is an ongoing project, which is set to transform medicine by integrating a genomics approach to diagnosis and therapy; providing a much-needed personalised approach to give individual patients the most appropriate care.

Whilst a database of 100,000 genomes develops our understanding of population genetics, it doesn't tell the personal stories of genome

sequencing. We sequenced the genomes of 10 healthy individuals to identify any useful genomic information that might elicit a preventative approach to their future health needs, and filmed their expectations and reactions to their results.

We called this ambitious project: Love My Genome because, like family, you don't get to choose your genome. The participants agreed to share their experiences to help others better understand what it means to discover your genetic makeup – including both the insights and current limitations.

As with any small-scale project, the results could easily have been underwhelming - 'boring genomes, nothing to see here' - and for some of us, this was true. For others, the results were anything but boring, and were profound in their implications.

In filming our thoughts, reactions and feelings towards both the process and the results, the issues of privacy, the importance of family history, our future health, and the health of our children were all revealed.

What became clear was that interpreting the 'whole genome' in its entirety is simply an impossible task. For starters, what we understand to mean a 'whole genome' today is very different from what it meant twenty years ago when the first whole human genome sequences were published.

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**"Our genome is many things: It is the sum total of all our genes, it codes for the proteins that drive the chemical reactions in our bodies and the structures that keep us upright. It is the blueprint that sketches out aspects of our appearance, our health and our behaviour; it contains shadows of our evolutionary past."**

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In only a few years' time, we are likely to know much more than we do today, so it is important to see one's genome as an evolving resource, some of which will have importance and significance today whilst other information may be beneficial only when sufficient research is available to put the results into a meaningful context.

Furthermore, even the most eminent molecular biologist will focus on their own specific area of expertise and view their genome through a narrow lens according to their own expectations and concerns. There is a gene on

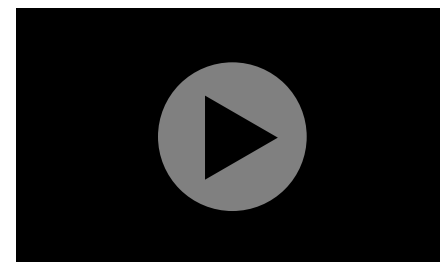
chromosome 1 (RPA1) that, when mutated, can cause tunnel vision in the literal sense - retinitis pigmentosa. In many ways, even the most educated of us can have an aspect of tunnel vision when it comes to our own lives.

In the film, one participant speaks of a change in her attitude towards sun exposure based on an increased risk of melanoma (aggressive skin cancer). By her own admission, it took a genetic test result to take this risk seriously, despite having pale skin, blue eyes and blonde hair. Her husband's test results revealed lactose intolerance which very clearly explained his immense discomfort when drinking milk and has steered him in the direction of non-dairy alternatives.

Of more direct clinical consequence were two other stories that focussed on breast cancer risk. We hear from a mother of four relieved to discover no specific cancer mutations in her genome, despite losing her own mother to breast cancer at the age of 60. The other side of this coin sees a father of three discovering a paternally inherited BRCA1 mutation, which, along with increased risk of breast, prostate and pancreatic cancers for himself, could have significant implications for his adult daughters.

While a challenging result for this family (especially since those same daughters lost their mother to breast cancer at the age of just 44) comprehensive screening and timely therapeutic intervention could save their lives should they too have inherited the mutation. These two contrasting results could both be considered good news stories if the information provided is used wisely.

The final twist in the tale is this: This particular group of unrelated healthy



individuals were all invited to participate because they have specific expertise in the world of genomics. They range from genetics professors to clinical scientists specialising in genetic screening; from a biotech developer to a lawyer who specialises in reproduction and genetics.

Michael Gove famously said: "I think the British people have had enough of experts." Our own experts discovered the need to reach beyond their expertise when confronted with life-changing information that could impact them, their families and their futures.

University of  
**Kent**

**Darren K Griffin**

**Professor of Genetics**

University of Kent, School of Biosciences

Tel: +44 (0)779 302 8711

[d.k.griffin@kent.ac.uk](mailto:d.k.griffin@kent.ac.uk)

<https://www.kent.ac.uk/biosciences/people/1244/griffin-darren>

[www.twitter.com/darrenkgriffin](https://www.twitter.com/darrenkgriffin)

**Alan R Thornhill,**

**Honorary Professor of  
Reproductive Genetics**

Igenomix UK Ltd and University of Kent

# Oxytocin, vasopressin and mother nature

Dr Sue Carter, The Kinsey Institute, discusses the critical role of oxytocin in birth, lactation and maternal behaviour and in tuning the baby's developing endocrine and nervous system

Like little scuba divers, most mammals begin their lives swimming in an intrauterine pool of amniotic fluid. Through a two-way tether, the umbilical cord, babies receive oxygen, nourishment and hormones, and transmit chemical signals to their mother. The mammalian infant also is being pre-programmed during pregnancy and by birth for life on "dry land." After birth, this programming continues in the form of hormones in milk and styles of parenting.

We now understand that one neuropeptide oxytocin, plays a critical role not only in birth, lactation and maternal behaviour – but also in tuning the baby's developing endocrine and nervous system. Oxytocin works in conjunction with an even more ancient chemical, known as vasopressin. Together these molecules are essential elements in adaptations to perinatal life and in the events surrounding birth.

## Birth and birth interventions

Birth presents one of life's most important challenges. Embedded in the perinatal period and birth experiences are biochemical messages that can help the infant feel safe, or alternatively prepare it for life in a threatening world. Yet, remarkably, the specific consequences of the birth experience itself for either mother or child's physiology and behaviour have received little attention.

Although a basic biological process, the birth transition is often subject to



medical and cultural modification. Hormonal treatments, including synthetic oxytocin (also known as Syntocinon or Pitocin) are widely used to induce or augment labour and protect against postpartum bleeding. Initially it was assumed that oxytocin produced by or given to a mother did not reach the infant in amounts sufficient to affect the child. The effects of oxytocin were believed to be transient, disappearing as soon as the hormone was cleared from the system.

However, studies in animals and humans indicate that oxytocin can cross the placenta around the time of birth and may be transmitted in mother's milk. We also now understand that endogenous oxytocin is an important factor in normal development, with long-term effects on brain maturation as well as in the capacity to manage stress, the autonomic nervous system and immune system.

In a search to better understand the developmental role of oxytocin, we have experimentally administered extra hormone, or in some cases injected agents that block the oxytocin receptors. Treatments were given just before birth via the mother or directly to the infant just after birth. These studies were conducted in the highly social prairie vole, a rodent species that shares with humans, "social monogamy" – a lifestyle characterised by a high level of sociality and the tendency to form families constructed around a mother, father and sometimes several generations of offspring. In prairie voles, and likely in humans, patterns of parenting play a role in sculpting expression of later behaviours, including later tendencies to form social attachments or care for infants.

Oxytocin plays a central role in many features of maternity, including synchronising social interactions and



attachment between mothers and infants. Oxytocin has a wide breadth of functions including effects on social behaviour, metabolism, cardiovascular function, immunity, and the autonomic nervous stress. Oxytocin through its effects on birth and lactation, allowed the development of large primate brains and eventually supported human evolution and cognition.

Vasopressin is a more primitive hormone, related to oxytocin and like oxytocin, is designed for change. Our work in prairie voles revealed that a single exposure to oxytocin on the first day of life could down-regulate the vasopressin receptor in brain regions involved in aggression. The one brain area in which oxytocin increased the availability of the vasopressin receptor was a region associated with pair bonding and reward. Such changes seemed to produce a more social male, better prepared to form social bonds and give sensitive care to his own offspring or siblings.

## The Goldilocks Principle

However, like the desired temperature of porridge in the children's tale, Goldilocks and the Three Bears, there is a "just right" range of experiences and hormones in early life that promote survival and reproduction. In our studies of prairie voles, we discovered that even apparently small events, such as a momentary disturbance of the family within the first day of life created life-long differences in brain development and the genes for the oxytocin receptor.

As one example, young prairie voles exposed to moderate social stimulation in early life are gregarious. In comparison to less social species of rodents, prairie voles begin life with more oxytocin, both in their blood and brain, and more oxytocin receptors in brain regions necessary for

social awareness and attachment. Prairie voles exposed to a single oxytocin treatment around the time of birth also showed – in later life – an even friendlier behavioural pattern with less anxiety and fear of novelty.

In some cases, neonatally oxytocin-treated voles also formed adult pair bonds more quickly. Especially in males, increases were seen in the oxytocin receptor after receiving small amounts of exogenous oxytocin, possibly allowing these males to be more sensitive to the benefits of oxytocin. The biological basis of the "Goldilocks principle" includes re-programming of neural pathways that rely on oxytocin and vasopressin.

## Should we "mess with mother nature?"

Prenatal and postnatal experiences differ among species and within a species among individuals and between the sexes. Variations in early stimulation and hormones, such as oxytocin contribute to these differences.

Moreover, oxytocin and perinatal social experiences also are widely manipulated. Among these manipulations are different styles of parenting, and birth interventions, such as Caesarean-sections, applications of extra oxytocin to hasten birth, or blocking oxytocin receptors (sometimes used to prevent premature labour). All of these hold the potential to influence a broad range of processes relevant to the health of both the mother and baby.

Perhaps even more remarkably, the genes that control the oxytocin receptor can be epigenetically "tuned" by either experience or hormones, including oxytocin itself. Birth and oxytocin both sculpt the brain and body. During the perinatal period infants receive behavioural and phys-

iological messages that help the new born adapt to and cope with an everchanging environment.

However, these properties also give birth, parenting and natural and medically-manipulated oxytocin the power to alter physiology and behaviour for both the present generation and into the future. Studies of oxytocin-vasopressin pathways are offering new insights into the pervasive health benefits of optimal early experiences. This research also provides warnings that manipulations of these systems hold the potential for unexpected outcomes.

We gratefully acknowledge support for research described here from the National Institutes of Health (P01 HD 07575) and the Fetzer Foundation.

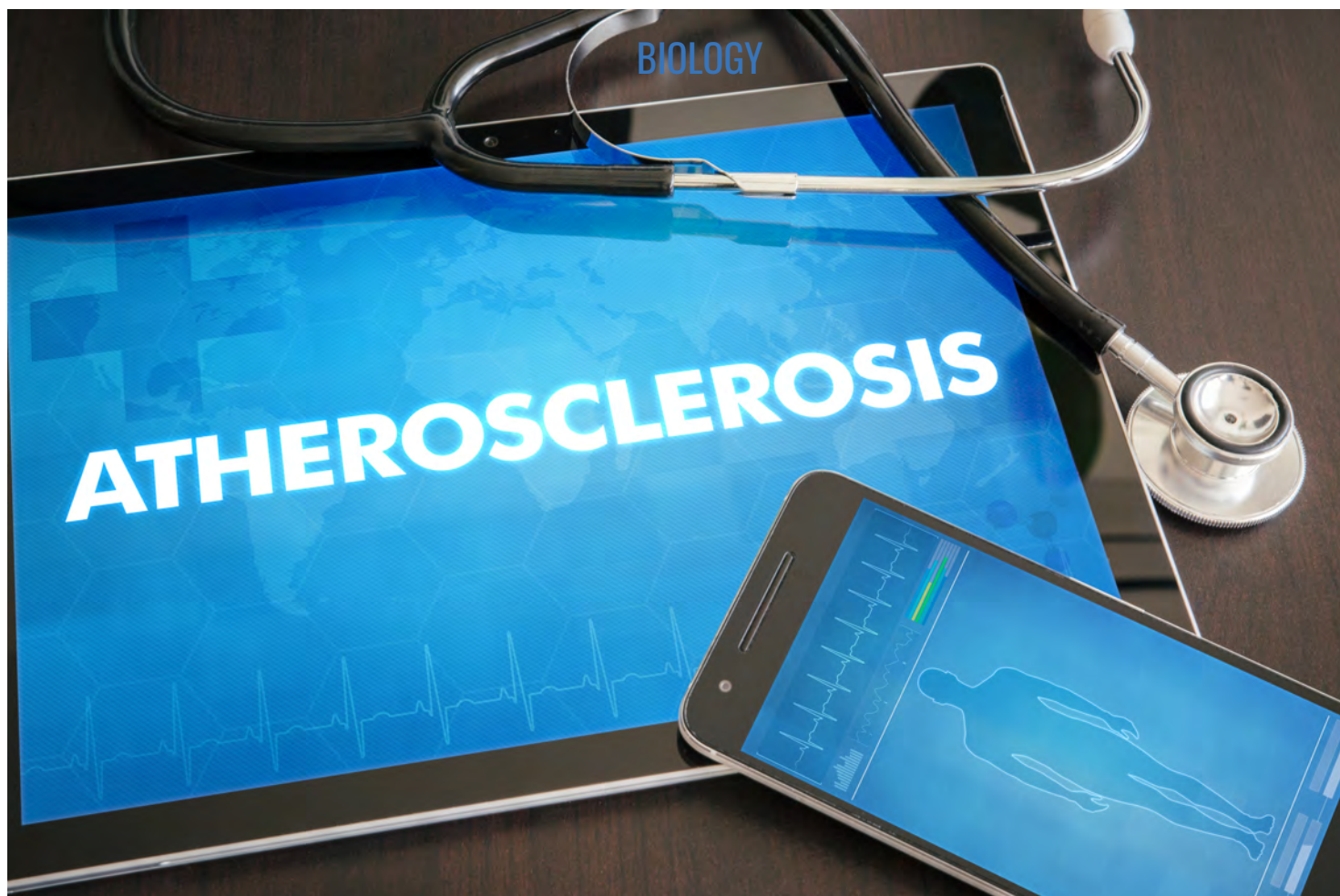
Suggested reading.

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**Dr Sue Carter**  
**Director**

The Kinsey Institute  
Tel: +1 812 855 4180  
[csccarter@indiana.edu](mailto:csccarter@indiana.edu)  
<https://biology.indiana.edu/about/faculty/carter-sue.html>



# Exploring the emerging role of tumour necrosis factor receptor-associated factor 6

Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group explores the emerging role of tumour necrosis factor receptor-associated factor 6 including the challenges and opportunities in this vein

**B**oth inflammatory and immune signaling have been recognised as a foundational root in a broad spectrum of cardiovascular pathologies. Recent studies exploring the emerging role of tumour necrosis factor receptor-associated factor 6 (TRAF6)-nuclear factor kappa B (NF- $\kappa$ B) signaling axis have established a clear relation between these associated factors and cardiovascular conditions, including atherosclerosis, ischemic heart disease, heart failure, hypertrophic cardiomyopathy (HCM) and sepsis-induced cardiomyopathy, among many others (Abdullah et al., 2018).

According to the authors, a deeper knowledge around cardiac inflammation and heart disease have allowed

to introduce the TRAF6 signaling axis as the core factor, directly related to the pathophysiology of heart disease. Such a profound understanding is driving to the development of new therapeutics that proposes TRAF6 as a novel, druggable target in treating cardiovascular disease incurred by inflammatory processes. By blocking TRAF6 cardiac dysfunction could be significantly attenuated.

Furthermore, TRAF6 has been suggested as an essential regulator of human stem cell (HSC) homeostasis through basal activation of NF- $\kappa$ B. Indeed, studies have demonstrated that hematopoietic-specific deletion of TRAF6 results in impaired HSC self-renewal while revealing changes in adaptive immune signaling, innate

and NF- $\kappa$ B immune signaling. These factors indicate that TRAF6 critically is required for HSC homeostasis (Fang et al., 2018).

### Innovations and solutions

TRAF6 is also being assessed as a biomarker of pathogenesis in immune thrombocytopenia (ITP), an acquired disease associated with several pathogenetic mechanisms. According to recent studies, TRAF6 levels were observed to be higher than healthy controls, therefore, suggesting a strong correlation between TRAF6 and ITP pathogenesis (Asoglu et al., 2018).

**“A deeper knowledge around cardiac inflammation and heart disease have allowed to introduce the TRAF6 signaling axis as the core factor, directly related to the pathophysiology of heart disease. Such a profound understanding is driving to the development of new therapeutics that that proposes TRAF6 as a novel, druggable target in treating cardiovascular disease incurred by inflammatory processes.”**

Yes-associated proteins (YAP) are known to modulate the activation of endothelial cells while suppressing vascular inflammation through preventing TRAF6-mediated NF- $\kappa$ B activation. This fact presents the remarkable importance in limiting the severity of sepsis-induced inflammation and organ failure (Lv et al., 2018). Based on this understanding, the strength and magnitude of endothelial activation and vascular inflammation could be precisely modulated opening a new avenue for novel therapeutics (Liu et al., 2018).

Returning to atherosclerosis, understood as one of the most relevant underlying causes of cardiovascular diseases, is driven by costimulatory CD40-CD40L receptor/ligand. Whereas the inhibition of CD40-CD40L strongly reduces atherosclerosis, long-term administration of CD40-CD40L inhibitors results in immune suppression and/or thromboembolic events. However, CD40 recruits TRAF6 to elicit intracellular signaling. Small molecule inhibitors (SMIs) that selectively block CD40-TRAF6 interactions, better known as TRAF-STOPS, play a leading role in ameliorating both atherosclerosis and restenosis, by reducing inflammation, without causing immune suppression (Seijkens et al., 2018).

### Final remarks

TRAF6 mediates several endothelial dysfunction mechanisms. An in-depth understanding of TRAF6 interaction with immunomodulators is opening novel paths for therapeutic interventions, helping to ameliorate atherosclerosis, cardiovascular disease and metabolic disorders by targeting TRAF6. ■

### Acknowledgements

I would like to thank all contributors from the industry involved with the development and delivery of this article from the TechVision Group at Frost & Sullivan.

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### Cecilia Van Cauwenberghe, PhD, MSc, BA Associate Fellow and Senior Industry Analyst

TechVision Group, Frost & Sullivan

cecilia.van Cauwenberghe@frost.com

ww2.frost.com

www.twitter.com/Frost\_Sullivan



# Ophthalmology: A focus on uveitis – the inflammation of the uveal tract

Dr Gerry Morrow explains what you need to know about an aspect of ophthalmology called uveitis, defined as inflammation of the uveal tract, which comprises the iris, ciliary body and choroid

**H**ow easy is it to diagnose sub-types of uveitis? Uveitis is defined as inflammation of the uveal tract, which comprises the iris, ciliary body and choroid. Inflammation may be more generalised to include the retina, the optic nerve, and the vitreous humour, known as panuveitis.

This inflammation can be acute, recurrent or chronic. The most commonly affected age group is between 20-60, but it can also affect children. There are a multiplicity of causes of uveitis, including autoimmune disorders, cytomegalovirus and other infections.

Symptoms and signs can be insidious and subtle, they include redness of the eye, pain, photophobia, a watering eye and sometimes (but not always) reduced vision associated with sluggish pupillary reactions. The diagnostic problem for clinicians is three-fold:

- There is a very long list of differential diagnoses, including relatively innocent causes of red-eye, including simple and common viral conjunctivitis.
- A slit lamp examination is required (and the associated expertise) to make a substantive diagnosis.
- This is a relatively rare condition; a GP may see fewer than one person a year with a new diagnosis of uveitis.

Early diagnosis is crucial to prevent the possible complication of visual loss due to secondary macular oedema, cataract and glaucoma.

Given all of these problems how easy is it to make a definitive subtype diagnosis of this important and problematic condition?

According to a paper in the American Journal of Ophthalmology, the answer is 'not very easy.' The authors set out to measure how likely uveitis experts were to agree on a diagnosis of sub-types of uveitis in 5766 patients. 76 investigators and nine committees

reviewed case notes and images for all these patients and reported on how much agreement on a specific diagnosis there was between reviewers.

Their analysis relied on the concept of measuring inter-rater reliability, which is the correlation statistic kappa (k). If  $k = 1$  this means that both clinicians agree exactly on a diagnosis. If  $k = \text{minus } 1$  then there is complete disagreement. Most research is based on figures of  $k = 0.81$  to 1 as providing 'almost perfect' agreement.

In the uveitis interobserver agreement paper, it was found that even amongst uveitis experts' variability was only 'moderate at best' as the whole series of 5766 patients,  $k = 0.39$ , with a range of 0.23-0.79. It was only when teleconferences were organised to create a consensus between clinicians that the variability correlation was moved much closer to complete agreement.

Crucially this agreement has fed into a final dataset for machine learning in order to assist the development of clearer diagnostic criteria for each diagnostic class of uveitis.

It is hoped that this work will help GPs and other clinicians in their diagnostic challenge of managing patients with visual symptoms in order to exclude or refer people with possible uveitis. ■

**Dr Gerry Morrow**  
**Medical Director**

Clarity Informatics

Tel: +44 (0)845 113 1000

[www.clarity.co.uk](http://www.clarity.co.uk)

[www.linkedin.com/in/gerrymorrow](https://www.linkedin.com/in/gerrymorrow)

[www.twitter.com/Clarity\\_hi](https://www.twitter.com/Clarity_hi)

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# Supporting vision research in the U.S. that encompasses visual impairment diseases

Here, Open Access Government explore how the National Eye Institute in the U.S is supporting vision research that encompasses visual impairment diseases of people of all ages

The National Eye Institute (NEI) was established on August 2nd, 1968. The U.S. Congress passed Public Law 90-489, which authorised the formation of the institution. It was President Lyndon B. Johnson, who signed the legislation on 26th December of the same year, at which moment the NEI began to function. The NEI has supported research into vision consistently, through around 1,600 research grants and conducting their own research that encompasses the visual impairment diseases of people of all ages.

Currently, Dr Paul A. Sieving is the NEI Director. During his time, he has established a programme to develop treatments for eye diseases, the NEI Audacious Goals Initiative (AGI) for Regenerative Medicine – this research focuses on how to restore the function of critical nerve cells in the eye and visual processing system. Dr Sieving particularly focused on these systems after they are damaged by disease, searching for strategic ways to reverse vision loss in age-related macular degeneration and glaucoma.

The NEI has created many research outputs, three of which we discuss below:

## **Zebrafish can regenerate from blindness**

An NEI study in 2017 examined how decreases in neurotransmitter GABA trigger stem cell production in the retina, which used blind zebrafish to attempt a reversing of the injury. They explored regeneration in the zebrafish retina, which happens naturally. Meanwhile, in humans, the same injury seems irreversibly damaging. The scientists found that GABA could be the influential factor in the regenerating process. This finding translated to human eyes could prove to be substantially useful.

## **Children can survive epilepsy surgery with full vision**

Recently, in June 2019, an NEI-funded study explored the

impact of brain surgery to halt seizures. The procedure is famously risky, with the understanding that visual perception could be significantly impaired. A new report from Carnegie Mellon University in the U.S. presented a study of children who had undergone the surgery, which then revealed that the lasting effect on visual perception could actually be imperceptible – even when the children had tissue in their visual centres taken away.

## **Nitisinone increases melanin in people with albinism**

A clinical study in February 2019 happened at the NEI itself, to suggest that the drug Nitisinone increases melanin production for some individuals who have oculocutaneous albinism type 1B (OCA-1B), which causes pale skin, hair and poor vision. A Melanin increase could significantly protect people with this condition against the UV rays of the sun. The scientists found a darkening skin and hair but are hoping to pursue a darkening of the imaging of the iris, over time. This could change the lives of people who currently have no cure.

The last word goes to Paul A. Sieving, Director of the National Eye Institute, who comments on the possibilities of NEI: “This is a remarkable time of discovery. We can view the functioning eye in greater and greater detail and gain a better understanding of the biology, at the level of cells, genes and proteins, that makes vision possible – and how things can go wrong with disease or trauma.”<sup>1</sup> ■

<sup>1</sup> [https://nei.nih.gov/sites/default/files/pdfs/NEI\\_Anniversary\\_History\\_Book.pdf](https://nei.nih.gov/sites/default/files/pdfs/NEI_Anniversary_History_Book.pdf)

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# Understanding chronic autoimmune uveitis through ophthalmology research

Andrew Taylor, Professor of Ophthalmology, highlights the research involved to help understand the molecules that mediate ocular immune privilege so they can be adapted as therapy for chronic autoimmune uveitis

**C**urrent therapy uses steroids, which have been the standard approach for over six decades. The recent use of humanized antibodies, biologics, to suppress key cytokines in the inflammatory pathway is providing an alternative to steroids; however, like steroid therapy carry serious side-effects from susceptibility to infection to even death. Ironically steroid therapy carries the risk of sight-threatening cataracts and glaucoma.

Nearly 17% of patients suffer chronic uveitis and are resistant to steroid therapy. This leaves them with months to years of finding the right concentration of a biological to manage uveitis with minimal side-effects. The objective of this therapy is to suppress inflammation to give the ocular tissue a chance to recover, and possibly reassert its normal anti-inflammatory mechanisms. Meanwhile, each episode of uveitis further diminishes vision leading to blindness and reduced quality-of-life.

One of the ultimate goals of autoimmune disease therapy is to find an approach that would return the immune system to treating our own tissues as self. Such a therapy would not only suppress inflammation; it would induce what could be considered hitting the reset button of the immune system to prevent recurrence of autoimmune disease. Studies into the mechanisms of ocular immune

privilege are revealing molecules that have the potential to reset immunity. Not only can these molecules be used as therapy, but they are also well tolerated and are molecules naturally expected to be expressed in a healthy eye.

Originally, the concept of ocular immune privilege was a transplantation term defined by Sir Peter Medawar as a tissue site where incompatible grafts survive indefinitely. Today, the definition of immune privilege includes a tissue microenvironment that actively suppresses the induction of inflammation and promotes immune tolerance. Immune tolerance is where immune cells regulate the activity of other immune cells.

Immune privilege is mediated by molecules expressed on cell membranes and secreted by cells within the eye. The result is that for most of us we have a lifetime of vision not threatened by inflammation and autoimmune disease. Our studies into these molecules of ocular immune privilege have demonstrated the role of several that hold a central role in ocular immune privilege and a role in immune regulation systemically.

One of these molecules is the neuropeptide alpha-melanocyte stimulating hormone ( $\alpha$ -MSH) and its melanocortin receptors (MCR). This neuropeptide first described for its

ability to regulate pigmentation has roles in metabolism, immunity, and general wellbeing. It and its receptors are highly conserved and are expressed in every animal. When we started studying the soluble molecules of ocular immune privilege, we had found that aqueous humour, the fluid that fills the anterior chamber of the eye, did not suppress T cell activity. It changed T cell activity from proinflammatory to anti-inflammatory.

Of the many molecules we found in aqueous humour that suppress inflammation, only  $\alpha$ -MSH made T cells expected to mediate inflammation suppress inflammation. In addition, we found that  $\alpha$ -MSH like aqueous humour makes other activated immune cells, like macrophages, to make anti-inflammatory cytokines and suppress inflammation. Removal of  $\alpha$ -MSH from aqueous humour eliminated the ability of aqueous humour to mediate anti-inflammatory activity. The results alone are enough to support melanocortin-based therapies to suppress uveitis; however, while we were studying the use of  $\alpha$ -MSH in therapy more was discovered, suggesting that melanocortin-based therapy can promote immune tolerance, the necessary reset of immunity.

The best-used mouse model of autoimmune uveitis is called experimental autoimmune uveoretinitis (EAU). EAU has served as an important





model in understanding the activity of immune cells in autoimmune disease, testing for new therapies, and understanding the mechanisms of immune privilege. One interesting feature of this model is that unlike in humans, mice resolve uveitis on their own without intervention with resistance to a recurrence of the disease. An important feature of post-EAU is the expansion of regulatory T (Treg) cells specific to antigens within the eye. We found that  $\alpha$ -MSH mediates the expansion of these eye-specific Treg cells.

Moreover, we found that  $\alpha$ -MSH through the melanocortin five receptor (MC5r) activates an antigen presenting cell (APC) that in a process called counter-conversion converts T cells that would mediate autoimmune disease into T cells that suppress autoimmune disease. These T cells are called inducible Treg cells, and they protect against reactivation of EAU. Treatment of EAU with  $\alpha$ -MSH accelerates recovery

from EAU, induces the expansion of the inducible Treg cells, and protects retinal structure from inflammation. The melanocortin-based therapy may very well reestablish ocular immune privilege. Even if  $\alpha$ -MSH is one of many molecules of immune privilege with the ability to induce tolerance, our findings demonstrate that using the melanocortin pathway is potentially an effective therapeutic approach to treat autoimmune uveitis, and preserve vision.

The molecular mechanisms of ocular immune privilege are a wealth of potential therapies to be exploited to suppress uveitis. Our findings that activation of the melanocortin pathway through the neuropeptide  $\alpha$ -MSH is not only essential for ocular immune privilege but that it can be used to suppress autoimmune uveitis. This is a new therapeutic approach using our body's natural molecules of ocular immune privilege, in our studies the neuropep-

ptide  $\alpha$ -MSH, to change the behaviour of immune cells to suppress inflammation, and autoimmune uveitis. In addition, there is a strong possibility that melanocortin-based therapy moves us closer to the ultimate goal of resetting immunity to prevent and stop chronic autoimmune uveitis.

**BU** School of Medicine

**Andrew W Taylor**  
**Associate Dean of Research,**  
**Professor of Ophthalmology**  
 Boston University School of Medicine  
 Tel: +1 617 358 2311  
[awtaylor@bu.edu](mailto:awtaylor@bu.edu)  
<http://www.bumc.bu.edu/ophthalmology/research-programs/andrew-w-taylor-phd/>

# Exiting the trade maelstrom in a progressive way

Vassilis Ntousas, Senior International Relations Policy Advisor at the Foundation For European Progressive Studies shares his thoughts on exiting the trade maelstrom in a progressive way

Over the past decades, international trade has been a significant factor in stimulating growth, encouraging job creation and promoting better living standards. Worldwide trade liberalisation has led to the creation of new wealth, new innovation and new opportunities in the global economy, bringing substantial benefits in terms of increased productivity, efficiency and revenue. Trade agreements have emerged as a key tool for further economic integration and cooperation.

At the same time, however, the consensus that the impact of international trade can only or primarily be positive has been (rightfully) broken. Tied to a form of untamed, unregulated globalisation, its results have at times been uneven, unequal and ultimately unjust for broad swaths of the population: exacerbating economic, societal and environmental inequalities and producing 'losers' in terms of jobs and incomes, not compensated adequately for their losses. Trade negotiations have also been often conducted in an opaque way, with the interest of the top income groups in mind, resulting in the erosion of rights and standards.

In our rules-based open global economy, international trade is, therefore, neither a panacea nor a predicament in itself. Similarly and especially against the backdrop of the experience of the last few years, it is now clear that the consequences of international trade are never neutral: trade is essential for growth, jobs and competitiveness, as much as it can have a profoundly negative impact on the ground if left improperly regulated or managed. Put more simply, countries might benefit from trade as a whole, but these benefits are unequally distributed, with certain people almost never being the recipient end of them: being left behind, facing the spectre of sudden unemployment, often displaced by competition from cheaper imports, dealing with painful adjustments to their livelihoods, ultimately

being structurally blocked from taking advantage of the prosperity that trade can offer.

Precisely because trade is not a neutral process, but its impact – positive or negative, wide or narrow, deep or superficial – depends on the policy character and direction given to it by those in power, there is profound political responsibility in recognising the challenges that exist in ensuring that global trade is truly free and fair and in guaranteeing that its positive side is evenly harnessed and experienced.

Solving this admittedly delicate equation puzzled the progressives for long. The last decade has exposed many fissures within the progressive camp, with parts of the movement exaggerating the benefits of trade, but underestimating its costs and others doing the precise opposite. This led to a lack of a clear political response to the gross unevenness with which many of trade's benefits have been distributed as well as to the web of inequalities that have spun wide and deep within our societies due to this.

Learning from the mistakes of the past and, therefore, updating and modernising the content of policy to meet the challenges not of yesterday, but of today and tomorrow, has also been a difficult undertaking. Nonetheless, intelligent and intelligible compromise positions are finally arising within the progressive camp, recognising that: "between the faithful and unconditional promoters of free trade and the populist critiques defending protectionist and nationalist visions of the world, there is a critical political space for progressive forces to defend a regulated vision of globalisation".<sup>1</sup>

Credibly occupying and actively defending this space is equally critical. The Trump administration's trade histrionics and his extremely risky tit-for-tat approach with



China are only part of the picture which explains the urgency of the moment. With trade war rhetoric ramping up globally and with tariff offensives proving increasingly painful for citizens, consumers and companies, how can social justice be promoted at the national, regional and global level? With many hitherto champions of (trade) multilateralism actively working to undermine the system, including at the World Trade Organization (WTO) level, how can we ensure that the global system fairly represents the interests of all countries, big or small? With the U.S. but also other countries seeking quick bilateral trade gains at the expense of their support towards this multilateral system of negotiations and settlements, how can we restore trust to the system instead of falling back to an almost reflexive state of protectionism? And for that matter, in this climate, how can we guarantee increased transparency in negotiations and decrease the influence of the corporate agenda, which usually takes place through means fair or foul?

These are rhetorical questions, of course.

Allowing a resurgent, assertive form of protectionism (and its pernicious twin, nationalism) to dominate our global thinking and practices, we can bid farewell to any semblance of having important global progressive causes and objectives, such as the Sustainable Development Goals, materialise and succeed. What is more, inaction in the face of the perilous pas de deux that is currently unfolding and falling into the trap of retaliatory actions can deepen economic anxieties and inequalities, unnecessarily stripping societies of

the benefits of trade while fuelling anti-democratic sentiments in many of our countries.

This is not a Cassandra-like set of warnings; looking back to the 1930s can easily offer a bitter sense of déjà vu when considering recent developments. Trying to weather this perfect storm that seems to be brewing, progressives need to grasp both the sense of urgency and their historic responsibility in reversing the situation. Crucially, this needs to happen not in any way and at any cost. Navigating and exiting the current trade maelstrom, these efforts should not be guided by an abiding faith in trade's potential in spurring prosperity under any circumstances, but by a nuanced understanding that compromises need to be made so that the global trade regime is not only defended but also refashioned towards a more progressive direction; a direction that ensures that trade works for all of society. ■

1. [https://www.feps-europe.eu/attachments/publications/international%20trade%20and%20investment\\_ok\\_s.pdf](https://www.feps-europe.eu/attachments/publications/international%20trade%20and%20investment_ok_s.pdf)

**Vassilis Ntousas**  
**Senior International Relations Policy Advisor**

Foundation For European Progressive Studies

[vassilis.ntousas@feps-europe.eu](mailto:vassilis.ntousas@feps-europe.eu)

[www.feps-europe.eu](http://www.feps-europe.eu)

[www.twitter.com/FEPS\\_Europe](https://www.twitter.com/FEPS_Europe)

[www.twitter.com/VNtousas](https://www.twitter.com/VNtousas)



# Cities proving to be the real climate champions

Anna Lisa Boni, Secretary General, EUROCITIES provides an absorbing insight into how cities in Europe are proving to be the real climate champions

**A**t a time when European leaders seem to be ignoring the urgency of our current climate challenge, cities are leading the way on efficient emissions reduction and building a greener, more sustainable and inclusive future for all. Two recent actions involving EUROCITIES member cities underscore this commitment.

At a signing ceremony in Genoa, 12 more big European cities committed to achieving at least 40% carbon emissions reduction by 2030. In doing so, the cities upgraded their commitment under the Covenant of Mayors initiative, which today gathers more than 8,800 local and regional authorities across 57 countries.

More recently, mayors and leaders of 210 cities across Europe, representing 62 million citizens sent a joint letter to European and national leaders urging them to step up the European Union's climate commitments, to show global leadership and drive ambition to make rapid progress in the implementation of the Paris Agreement.

## Local climate action plans

As local administrations, we want to contribute to a strong European Union (EU) that lives up to its Paris Agreement commitments. Achieving the goal of keeping down global temperatures needs action at the local level – where the vast majority of climate legislation must be implemented. By stepping up to these commitments and developing local climate action plans, many cities are showing a higher level of ambition than their national and EU level counterparts. There are many ways we can do this.

Urban transport accounts for roughly 40% of all CO<sub>2</sub> emissions from road use and passenger cars make up by far the most amount of traffic on our roads. This has



*Anna Lisa Boni, Secretary General*

obvious effects on people's physical, social and mental wellbeing through noise, accidents, pollution, as well as lack of space and exercise.

One of the ways cities can live up to their green ambitions is by developing sustainable transport measures and contributing to EU research and policy recommendations through our involvement in different EU and city-led projects. Cities face the double challenge of improving mobility while making urban transport

more sustainable. A sustainable urban mobility plan can stimulate behavioural shifts away from the use of private cars; although it must consider the needs and input of local people, businesses and other stakeholders.

Another way cities can contribute is to act as match-maker. City administrations work directly with citizens, businesses and civil society to implement actions, such as decarbonising heating and cooling, retrofitting buildings and increasing active mobility plans and low carbon transport.

Public procurement contracts can help influence the local value chain, while cities can also team up to jointly purchase new technologies, such as e-vehicles, thus, bringing down costs and speeding up the green transition.

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**“One of the ways cities can live up to their green ambitions is by developing sustainable transport measures and contributing to EU research and policy recommendations through our involvement in different EU and city-led projects. Cities face the double challenge of improving mobility while making urban transport more sustainable. A sustainable urban mobility plan can stimulate behavioural shifts away from the use of private cars; although it must consider the needs and input of local people, businesses and other stakeholders.”**

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Technology can help us live more resource efficient lives and cities provide the right scale to test out new solutions. ‘Smart lampposts’ can be fitted with sensors to monitor air quality, or excess heat from server systems can be used for district heating.

Such solutions and ideas can be shared through city networks like EUROCITIES. These ideas are then adopted or adapted by other cities, strengthening innovation and capacity building in our cities.

### Climate neutral by 2050

The recent revelations of the International Panel on Climate Change, to the effect that global warming is even more serious than was previously understood, have helped foster a global citizens movement for change. Meanwhile, the 28 draft national energy and climate plans submitted by EU Member States, reportedly fail to set out a clear path towards carbon neutrality by 2050.

Given local level commitment, it’s time for European and national leaders to start taking mayors more seriously as equal partners in designing national climate action plans, as well as during international negotiations. Such climate talks could take inspiration from the partnership approach of the Urban Agenda for the EU, which brings together representatives from cities, national governments and the European Commission to discuss urban matters. The partnerships focus on issues like the energy transition, climate adaptation, circular economy, urban mobility and innovative procurement, so the ground is already set for further development and the exploration of new collaborations in multilevel governance to tackle climate challenges.

As the closest level of government to citizens, city administrations are showing we know best how to deliver what people want. European leaders and other levels of government can learn a lot from this can-do approach of cities. It is said that true leaders emerge during times of crisis. Well, this is a crisis and cities are proving they are the true climate champions. ■

*EUROCITIES is the political platform for major European cities. We network the local governments of over 140 of Europe’s largest cities and more than 40 partner cities that between them govern some 130 million citizens across 39 countries. [www.eurocities.eu](http://www.eurocities.eu)*



**Anna Lisa Boni**  
**Secretary General**

EUROCITIES

Tel: +32 2 552 0888

[info@eurocities.eu](mailto:info@eurocities.eu)

[www.eurocities.eu](http://www.eurocities.eu)

[www.twitter.com/eurocitiestweet](https://twitter.com/eurocitiestweet)

# REGIONAL DEVELOPMENT IN SWEDEN

## THE STORY OF AN INTERNATIONAL DEVELOPMENT LAB

WHEN YOU PASS THROUGH THE DOORS OF THE ALEXANDERSON INSTITUTE IN SWEDEN, IT IS LIKE SETTING FOOT IN AN ADVANCED INTERNATIONAL DEVELOPMENT LAB. IN THIS HIGHER EDUCATION INSTITUTE, NEW AND EXCITING METHODS ARE CREATED TO PROMOTE FUTURE GROWTH, AS WE NOW DISCOVER

The Alexanderson Institute is a part of Centrum För Livslång Lärande (Cll), Municipality Of Varberg, Sweden. So, what is unique about our approach at the Alexanderson Institute? In a word, it's openness. Every window is wide open. We are always looking for the best sources of experience and knowledge, while continuously developing new tools. We mix everyday ingredients of many and varying kinds, and we are happy to let others contribute to the result. We season with untested approaches and new solutions. There is a great deal of fresh thinking in everything we do at the Alexanderson Institute.

But creativity does not automatically lead to success. Instead, development is driven by experimentation, while also letting those around us contribute, become engaged and judge what we do – often receiving a surprise or two in the process.

The important thing is that the results of these efforts provide insight, vitality and value to others. We want everyone who contributes to help ensure the results are passed on. That is how organic development is created.

## REVOLUTIONARY YEARS

Ten years have passed since the official opening of the Alexanderson Institute, or AI as we call it.

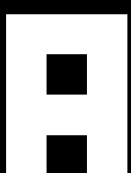
The concept of "Competitive Knowledge" is central to the Institute's philosophy. Our interpretation is clear: we always start from the conditions and needs of those around us before adding the value and benefit that is demanded. We have pursued this approach in real-life situations – with striking results. Right from the beginning, we had a strong position, enjoying goodwill within the EU-financed projects we participated in. And throughout these years, we have strengthened our position.

Today, we are seen as a potential partner in many of the development programmes that established organisations compete to take part in. The reason for this is largely thanks to the way we successfully deliver value for money.

It is through this funding and the tangible benefits offered by international networks that value is created for us in our region and in the regions we work with. It's about give and take – and building confidence between people.

## THE THREE WISE Ms

We are constantly striving to clarify not only our role in the complex interplay of synergies around the development of the region but also how business and public organisations can expect to benefit.



**Alexandersoninstitutet**





We explain this through our three Ms – mediator, meeting place and a motor for competitive knowledge. Our activities revolve around these concepts. The Alexanderson Institute facilitates the flow of knowledge, experience and competence. We offer an infrastructure for creating meetings and networks, which, in turn, generate new ideas, methods, business and returns. The motor, the third component, is a result of the other two.

## **A POSITION IN THE VALUE SOCIETY**

The Alexanderson Institute is located in the region of Halland, Sweden. This is where we have our roots and where we wish to share our success.

Equally important for the future is being part of the same value region. Today, value solidarity is even more important than physical solidarity – thanks

to the rapid growth of digital infrastructure. For the first time in history, groups of individuals, companies and organisations can establish value links in new ways.

Who is to say that a person or company, or even a municipality, derives the greatest benefit from its closest neighbours, when it is just as easy, or even easier, to maintain contact and exchange experience with kindred spirits on the other side of the world?

Thanks to its growing international networks, the Alexanderson Institute has created strong links to a value-based region. Every day, we meet people and organisations who are on the same wavelength as we are – and who want to partner with us in developing the future.

In Halland, we are the leading player in the new international value arenas. We open doors. We give all those in our networks access to these arenas. And this is just the beginning.

## **A GROWING KNOWLEDGE ORGANISATION**

The Alexanderson Institute and Campus Varberg are developing in tandem and have built up unique network-based structures. The Alexanderson Institute is in collaboration with governmental and regional platforms, municipalities, universities and national SME's, and is involved in several key EU projects. Campus Varberg through the university programme and vocational college, in conjunction with other seats of learning, are complemented by key contacts in business and the public sector.

# Mortality, work and migration: Male and female mortality from TB in rural and urban Victorian settings

Alice Reid and Richard Smith, Cambridge Group for the History of Population and Social Structure, Department of Geography, University of Cambridge explore the links between tuberculosis (TB) mortality, occupations, rural and urban residence and migration in late Victorian Scotland

The notion of the urban graveyard in which deaths exceeded births appears to have applied to most British and European towns and cities until at least the last quarter of the eighteenth century. Such urban settings were intrinsically unhealthy, requiring a constant influx of immigrants to sustain them. Furthermore, urban immigrants experienced increased mortality risk on their arrival, succumbing to infectious disease prevalent in such locations. Smallpox is viewed as one of those infectious diseases that was most fatal in its impact on urban immigrants of all social levels in the seventeenth and eighteenth centuries.

By the late 19th century, a greater incidence of chronic disease as a cause of death may have enabled the emergence of two different types of selection effects of migration upon mortality, termed 'the healthy migrant effect' and the 'salmon-bias effect'. The 'healthy migrant' suggests natural selection through which those moving from rural to urban locations were frequently healthier than their peers who remained in the countryside and when in towns they might display lower mortality than those who were urban born, even if mortality in their birthplace was higher than in the

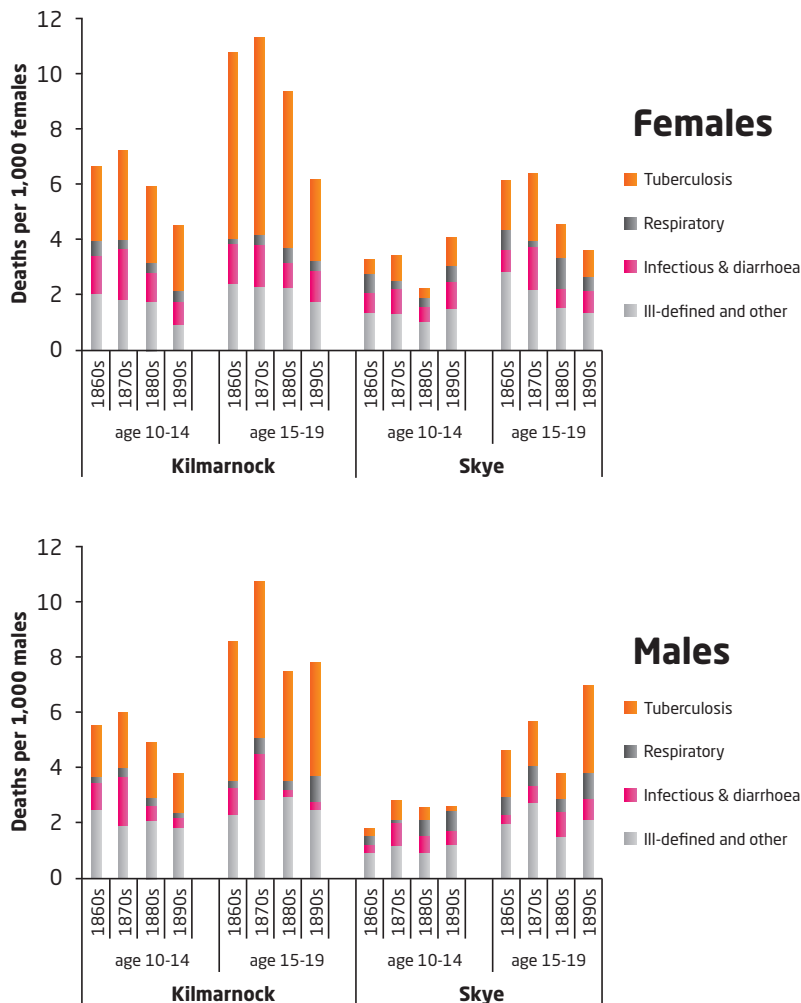
town. The 'salmon-bias effect' suggests that lower urban mortality is the result of selective return migration to the countryside of those who became diseased or acquired a chronic illness while those who remained healthy persisted in their urban residence. Rural locations will, therefore, have displayed higher mortality in part because of the return to them of those who had gone to towns within which they acquired chronic disease.

These hypotheses help to make sense of the geography of a chronic disease such as tuberculosis (TB), a leading cause of death over much of the life course in the latter half of the 19th century. TB has been the centre of various unresolved debates regarding urban-rural, occupational and sex-specific differentials in mortality in that period. There is disagreement about why women had higher death rates from TB than men and whether this was due to innate female susceptibility, poorer nutrition or differential exposure. One frequently encountered argument is that higher female TB rates were due to the weaker bargaining power of females within their households, a feature thought to apply to low wage agricultural areas where women had limited employment opportunities.

In contrast, some have suggested that high rural TB might be due to a salmon-bias effect caused by return migration of those who had contracted that disease in urban places. All of these claims have unfortunately been based on the use of aggregations of deaths recorded in civil registers and not on individual-level data from those same registers. Scotland provides a unique opportunity to use individual-level data from the rural Isle of Skye where agriculture and fishing were dominant and emigration was high and the fast-growing, industrial town of Kilmarnock which grew markedly in part through immigration. In both locations, nominative linkage was possible involving persons appearing in individual death, birth and marriage certificates with those same individuals listed by name, age, sex, occupation and birthplace in the decennial censuses between 1861 and 1901.

Absence from a census permitted the identification of individuals who had left either Skye or Kilmarnock following the previous census and new arrivals in these places could be identified in a similar fashion. It was possible to track the occupational status and migratory history of those dying at specific ages from TB. TB mortality

## Cause-specific mortality among adolescents in Skye and Kilmarnock, 1860s-1890s



in the age groups 10-19 was considerably higher in Kilmarnock than Skye and in Kilmarnock was significantly higher for females than males. This was almost entirely a result of the heavy involvement of women in cotton manufacture which created working conditions exposing them to TB. Although far fewer males worked in textiles, those that did were as vulnerable to TB-related deaths as females. This finding provides no support for the theory that young women were inherently more vulnerable to the disease.

Male death rates from TB were considerably higher than for females in Skye resulting from selective outmigration of healthy people, particularly

males, coupled with their return migration when chronically ill. The death certificates provided valuable information on the duration of the illness leading to death and for those dying from TB on Skye was 18 months to two years, giving sufferers time to travel home for care. Those suffering from acute infections would have had less opportunity and possibly inclination to migrate back to the communities of their birth from which they had emigrated. Rural locations which experienced higher out-migration of a particular sex were, therefore, more likely to experience higher mortality rates from all causes due to the loss of healthy emigrants and from TB, in particular, because return migrants were frequently unhealthy. This data

provides limited support for the bargaining-nutrition explanation and suggests that exposure to infection was of far greater significance.

Furthermore, the string of late Victorian industrial legislation bringing improvements in the working environment led to a fall in urban TB mortality. Simultaneously, those suffering from TB were hospitalised or entered sanatoria and were less likely to seek the care of kin in their rural birthplaces which had previously inflated the death rates of such locations. There are striking similarities with findings in more recent studies of Africa that have highlighted the inter-relationship between migration and mortality in the context of HIV/AIDS; a disease which like 19th century TB in Europe takes a relatively long time to reach a fatal conclusion.

This research is supported by The Wellcome Trust, grants 082200/Z/07/Z, Doctors, deaths, diagnoses and data: a comparative study of the medical certification of cause of death in 19th century Scotland and 103322/Z/13/Z, Migration, Mortality and Medicalisation: investigating the long-run epidemiological consequences of urbanisation 1600-1945.



**Richard Smith**  
 Emeritus Professor of Historical  
 Demography and Geography  
 University of Cambridge  
 Tel: +44 (0)1223 333 182  
 rms20@cam.ac.uk  
[www.campop.geog.cam.ac.uk/research/projects/migrationmortalitymedicalisation/](http://www.campop.geog.cam.ac.uk/research/projects/migrationmortalitymedicalisation/)



# Places with purpose: Reinvigorating Britain's town and city centres

Cllr Peter Box, Leader of Wakefield Council and Chair, Key Cities Group explains how Britain's town and city centres face significant challenges in redefining their purpose for local residents, visitors and businesses

Following a decade of overall economic downturn, shifting consumer patterns and technological advancements, Britain's town centres face significant challenges in redefining their purpose for local residents, visitors and businesses. Coupled with ongoing uncertainty around the impact of Brexit, our town and cities are now at a pivotal stage of their evolution.

As a group, Key Cities has a vital role to play in ensuring that the voices of Britain's towns and cities are heard. We achieve this by developing the agenda and policy asks for governments on behalf of our members – a diverse range of 24 medium-sized cities across the UK.

This mission was central to our recent research report: *'The Future of our City and Town Centres'*. The report focuses on the challenges and opportunities faced by our mid-size cities and township. Partnership and collaboration are at the core of our strategy, and the report includes a blueprint with best practice examples of how we are responding to these challenges.

Whilst many of Britain's larger cities have had a diverse mix of uses within their centres, many of the key cities developed to primarily serve local residents working in industry. Many of these industries have since reduced their scale or disappeared entirely in today's service-driven landscape. The shift in this trend has left a chasm in many of Britain's medium-sized cities, and they are left with no easily distinguishable assets.

This, alongside the fact that city and town centres across the UK are all impacted by the ever-changing retail, housing and leisure industries, means that we must develop innovative approaches that seek to use centres in a diverse way that delivers prosperity for local residents and businesses.

## Innovation within the retail industry

The retail industry is one sector where economic and consumer-spending habits are having the greatest impact. Whilst retail spend in the UK grew by 4.7% to £366 billion in 2017, online-only sales rose by 15.9% during the period, compared with a disproportionate 2.3% for bricks and mortar sales, according to the latest [ONS figures](#). With the prominence of online retailers continuing to grow, the threat to falling in-store sales is ever-present.

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*“Although our towns and cities face considerable challenges in their centres, it is not all doom and gloom. Collectively, we must remind ourselves that our centres primarily exist for people, through the provision of societal and economic benefits for all.”*

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The industry must consider how advancements in technology and innovation can transform existing processes and improve the overall experience for the customer and increase productivity rates at the same time. This can take many forms, through exploring the use of apps and in-store Wi-Fi, mobile payments and blockchain technology within the supply and logistics industry.

However, the future success of our town and city centres extends beyond the retail industry. In compiling our Town Centres research, we published the findings of our survey aimed at key cities residents to ascertain what their perceptions and priorities for the future of town centres were.

## Increasing connectivity

When asked about infrastructure, perhaps unsurprisingly, the majority of respondents cited initiatives with a digital dimension. Popular answers included electric



Cllr Peter Box

vehicle charging points, improvements to mobile network coverage and signposting way findings – including via digital tools. In this regard, the task for our centres is to embrace digital transformation and emerging technologies by ensuring that the supporting infrastructure is in place.

### Britain's diverse housing landscape

The housing market across the UK continues to paint a diverse picture, which is especially true for Key Cities. Despite overall housing numbers across member cities increasing steadily over recent years, the majority of city centre housing falls at the extreme ends of a spectrum. Either accommodation becomes unaffordable due to high land values in centres or, the abundance of low-quality housing dictated by housing benefit decreases the incentives to improve housing standards. In responding to this parity, we must ensure that engagement between local authorities, planning organisations and central government occurs, with the objective of providing housing that meets the diverse needs of local residents and communities.

### Creating places with purpose

Although our towns and cities face considerable challenges in their centres, it is not all doom and gloom. Collectively, we must remind ourselves that our centres primarily exist for people, through the provision of societal and economic benefits for all. For any response to be successful, we must ensure that the vision for our towns and cities is borne out of the needs of its custodians. We must also provide incentives for visitors to make a return visit, by providing them with a positive and enriching experience in our centres.

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*“As a group, Key Cities has a vital role to play in ensuring that the voices of Britain's towns and cities are heard. We achieve this by developing the agenda and policy asks for governments on behalf of our members – a diverse range of 24 medium-sized cities across the UK.”*

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Through our combined expertise and template for town and city centres to follow, Key Cities are primed to support policymakers and local authorities to ensure that the appropriate funding and initiatives are in place to ensure that city and town centres evolve for the better. ■

### Cllr Peter Box Leader of Wakefield Council

Chair, Key Cities Group  
[keycities@wakefield.gov.uk](mailto:keycities@wakefield.gov.uk)  
[www.keycities.co.uk](http://www.keycities.co.uk)

# Swindon and Wiltshire: Opportunities from economic shocks

How does a region respond having experienced two economic shocks in a year?

Paddy Bradley, Director at Swindon and Wiltshire LEP tells us more

**T**he economy of Swindon & Wiltshire has lived this reality with two major incidents declared in Salisbury and Amesbury in 2018 and in February of this year, Honda Manufacturing UK announced its plans to close its 370-acre site in Swindon in 2021.

As soon as the major incident in Salisbury was declared in March 2018, an initial recovery fund of £20,000 was set up with both the Swindon & Wiltshire Local Enterprise Partnership (SWLEP) and Wiltshire Council contributing £10,000 each. To provide further support, the SWLEP provided capital funding of £90,000 and the Department for Business, Energy & Industrial Strategy (BEIS) contributed £100,000. The capital fund provided grants to assist businesses that were adversely impacted including retailers, food and drink operators and those providing accommodation. The fund was for capital expenditure to support businesses in their recovery; including enabling them to refurbish and redevelop their premises and purchase equipment.

Salisbury and South Wiltshire are still being impacted by the Novichok attack last year. Footfall remains persistently below 2017 levels in Salisbury. Since the incident in March, there has been a 12% decrease in visits to the city, compared to a 2.4% decrease in footfall nationally through 2018. Salisbury has seen a drop of

circa 1m in footfall to the city centre, a drop of around 100,000 per month.

A strong partnership has been established to develop a long-term recovery strategy and programme of interventions to drive economic growth in the sub-region. The SWLEP is working with Wiltshire Council and partners on the development of the plan for a step-change in the economic performance of Salisbury and the region. Potential projects are being scoped that will not only support Salisbury but will have a significant impact on the economy of Wiltshire and Swindon.

The SWLEP is continuing to invest in the economy of South Wiltshire. Through the Local Growth Programme, over £6 million is being invested to transform The Maltings and over £13 million in the development of the Wiltshire College & University Centre campus. In the wider area of South Wiltshire, £4 million has supported the successful delivery of the first phase of the Porton Science Park, £1.35 million has been allocated to the proposed Royal Artillery Museum at Netheravon and businesses in parts of South Wiltshire are benefiting from a proportion of a £1 million investment in a roll-out of ultrafast broadband.

The SWLEP board has reallocated £1.1m from their Local Growth Deal fund to support projects proposed by the South Wiltshire Operations Board

that meet the economic outcomes sought by the SWLEP. This is subject to the approval of individual elements by the board and to date £650,000 has been approved to progress projects included in Wiltshire Council's bid to the Future High Streets Fund. The SWLEP is also launching a £500,000 loan fund particularly aimed at small businesses in Salisbury.

The unified response by businesses and partners to the economic shock in South Wiltshire demonstrated commendable resilience and there continues to be effective collaboration as everyone works together with a shared vision that reaches beyond recovery to creating an economy in South Wiltshire that is more vibrant than it was before the incidents.

The impact of Honda UK's announcement is being felt deep within the community of Swindon and surrounding areas. Honda's long association with the area means that many families know someone who works or has worked at Honda. Honda has been one of the largest and most important employers in the area since 1985 when Honda Manufacturing UK Ltd bought the old airfield in South Marston, Swindon. Over the last 30 years, more than 3 million cars have been manufactured at the site and the plant employs 3,500 people.

This is a decision with a national impact too, accounting for up to 10%





of UK car manufacturing and the associated supply chain that employs 10,000 people nationally. There will be knock-on effects into local businesses who are operating solely or in part because of Honda's contracts or the presence of its workforce. The Swindon & Wiltshire Local Enterprise Partnership is working closely alongside government, Swindon Borough Council and local partners to help deliver a plan of support for employees and businesses in the area.

As soon as the announcement was made, Swindon's community spirit and generosity came to the fore. Swindon Borough Council and partners were inundated with practical offers of support from businesses and individuals from across Swindon, Wiltshire and beyond.

The business secretary convened and co-chaired a taskforce in Swindon with the leader of Swindon Borough Council and the chair of the Swindon & Wiltshire Local Enterprise Partnership. This brought together our local MPs, civic and business leaders, as well as

trade union representatives.

Our aspiration is for the site to become home to several advanced manufacturing businesses, employing the highly skilled Honda workforce and diversifying the economy, as well as increasing productivity. In Swindon and across the UK, we have some of the best talent in the world and the government is already investing in future car manufacturing, batteries and electrification infrastructure to ensure the UK retains its world-leading edge. Last year at the Word Zero Emission Summit in London, the Prime Minister saw first-hand the zero-emission makeover of the iconic Mini that uses a modern electric powertrain designed and developed by local company Swindon Powertrain.

Through the Industrial Strategy and automotive sector deal, the government has set out a clear ambition to put the UK at the forefront of the design and manufacturing of zero-emission vehicles and for all new cars and vans to be effectively zero-emission by 2040.

The Hydrogen Hub launched in Swindon and Wiltshire in January 2016 and has driven external investment in hydrogen and fuel cell projects in the region, with over 50 different organisations participating in working groups and projects. That includes Swindon-based car leasing firm Arval UK, which plans to add 10 new company cars to a cutting-edge hydrogen trial with the opening of the town's second refuelling station near to its head office.



**Paddy Bradley**  
**Director**

Swindon and Wiltshire LEP  
[paddy.bradley@swlep.co.uk](mailto:paddy.bradley@swlep.co.uk)  
<http://www.swlep.co.uk/>  
[www.twitter.com/swlep](https://twitter.com/swlep)

# Diversity and interculturalism in cities worldwide

Diversity and interculturalism in cities worldwide are placed under the spotlight here by Dr Gideon Bolt, from the Department of Human Geography and Planning Faculty of Geosciences at Utrecht University in the Netherlands

Cities worldwide are becoming increasingly diverse, particularly as the result of globalisation and migration. This increasing diversification poses challenges for national integration policies, as well as urban planning. The assimilationist approach, viewing the otherness of ethnic communities as temporary, is increasingly problematic now that many large Western cities lack a clear majority group in which one is to assimilate (Crul, 2016). At the same time, there has been a backlash against the multiculturalist approach across Western Europe (Vertovec and Wessendorf, 2010).

Multiculturalism is accused of stressing cultural differences and reinforcing power inequalities. Wood & Landry (2008), for instance, argue that forming alliances with (often self-appointed) ethnic community leaders is part and parcel of the (British) multicultural model. These alliances have reified the idea of fixed ethnic categories and are partly responsible for the building up of tensions between ethnic groups. The (supposed) failure of multiculturalism, combined with the worries of politicians and voters about the increasing size and diversity of the immigrant population has led to a shift towards assimilationist policies, at least at the national level. This is visible in the adoption of civic integration policies across Europe, which reveals prioritisation of the national cultural identity

at the expense of the recognition of migrants' cultural identity (Joppke, 2007).

## Interculturalism

Critics of multiculturalism have put forward interculturalism as the preferable mode of incorporation (Tasan-Kok et al., 2013). The idea is that the focus of multicultural policies on the collective characteristics of people who are subject to discrimination accentuates the cultural differences on which their exclusion is based. This comes at the expense of the development of an overarching trust. Interculturalism is presented as a concept that tackles the shortcomings of both assimilation and multiculturalism.

Whereas assimilationism is critiqued for a lack of respect for diversity, interculturalism has a sensitivity to ethnocultural diversity in common with multiculturalism. At the same time, its proponents argue that interculturalism is more committed to creating a stronger sense of the whole (Meer & Modood, 2012). According to Cante (2012, p. 157) multiculturalism is about the co-existence of cultures, which reinforces differences, while interculturality is about 'a sense of openness, dialogue and interaction between cultures leading to long-term change in both relational and institutional arrangements'.

The claim that multiculturalism leads to parallel communities, as opposed to dialogue between cultures, is also supported by the argument that it treats members of ethnic minorities as "ever-representative of bounded collective" (Vertovec and Wessendorf, 2010, p.19). In the context of an increasingly diverse population, it is not feasible anymore to protect the heritage of different cultures and to communicate with community representatives to do so (Van Breugel et al., 2014). There is no one who can claim to be the spokesman of a community, when that community is fragmented and when identities become increasingly hybrid. Advocates of interculturalism argue that it is necessary to move beyond depictions of bounded communities differentiated along ethnic and cultural lines as it leads to essentialising of ethnic differences while overlooking other differentiations on the basis of class, lifestyles, attitudes or activity patterns (Tasan-Kok et al., 2013). Therefore, a shift is needed from the recognition of collective identities to that of individual competences. Consequently, mainstreaming is advocated as the best strategy for addressing a hyperdiverse society (Van Breugel et al. 2014).

## Mainstreaming

Collett & Petrovic (2014, p.3) describe mainstreaming as "the effort to reach people with a migration background



through social programming and policies that also target the general population, rather than through specific immigrant integration policies alone”.

Mainstreaming implicates that diversity policy is not the responsibility of a single department in a municipality, but that diversity-related efforts are integrated into the core services of all administrations in a municipality. Mainstreaming should not be seen as a colour-blind universal policy (which would fit in an assimilationist approach), but as diversity-sensitive policy that does not treat people solely as a member of an ethnic group. Toronto, a city which has adopted ‘diversity our strength’ as its motto, has a very broad understanding of diversity, including categories like seniors, youth, women, LGBTQ people, the urban poor, ethnic groups, disabled people, newcomers and immigrants, aboriginal peoples and the homeless (Ahmadi & Tasan-Kok, 2014, p.14).

## The role of cities

It can be argued that cities are suitable places for creating a stronger sense of

the whole. Wood & Landry (2008, p. 321) argue: “While people, migrants or not, find it increasingly difficult to find common cause with or a loyalty for a national state that does not recognise them and that pursues an aggressive and dubious foreign policy; but they do identify with the city where they live, work and interact.” One element of an intercultural approach, therefore, is to stimulate encounters with others in urban space. Fincher and Iveson (2008, p.145) plea that city life should enable “our capacity to explore different sides of ourselves and to craft new identifications through encounters with others as strangers”. Therefore, zones of encounters should be created, as interaction will not happen automatically (Wood & Landry, 2008).

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### Dr Gideon Bolt

Department of Human Geography  
and Planning  
Faculty of Geosciences – Utrecht University  
Tel: +31 302 531 399  
G.S.Bolt@uu.nl  
www.uu.nl/staff/GSBolt/O





# Why championing recycling can help to combat climate change

Ranjit Baxi, Bureau of International Recycling (BIR) President and Founding President of the Global Recycling Foundation, comments on the links between recycling and climate change, as well as the success of the celebrated Global Recycling Day 2019 on 18th March in cities around the world

**L**aunched in 2018, Global Recycling Day, an initiative of the Global Recycling Foundation (GRF), is a movement dedicated to celebrating the importance of recycling and making the world think resource not waste. Taking place on 18th March every year, Global Recycling Day saw events, campaigns and social media activity take place across the globe, reaching hundreds of millions of people.

We all appreciate the value of recycling in preserving our precious primary resources and now we're starting to see a new focus on the impact of recycling has in helping to reverse the effects of catastrophic climate change.

## **The growth in public perception of climate change**

Public consciousness is waking up to its pivotal role in preventing climate change, most dramatically witnessed by widespread protests taking place across the world in recent months. This has ranged from the activities of environmental activists, such as the protests organised by Extinction Rebellion over Easter Weekend, to everyday citizens. And earlier this year, the UK parliament became the first in the world to recognise a '[climate change emergency](#)'.

We've also seen a form of youth engagement like never

before, with school strikes around the world led by the now iconic Greta Thunberg. And back in December 2018, a landmark agreement was announced at COP24 in December 2018 which saw the world's governments agree to a robust set of guidelines for implementing the 2015 Paris Climate Change Agreement – representing a major step forward.

Throughout these strikes, discussions and events, recycling has at times taken centre stage. According to a study by the Finnish Innovation Fund Sitra and the European Climate Foundation, an improved circular economy is crucial in achieving the goals of the Paris Climate Agreement. And the recent Waste to Wealth Summit, spearheaded by HRH The Prince Of Wales's Responsible Business Network, was launched in November to eliminate unavoidable waste by 2030 and prevent catastrophic climate change. The Global Recycling Foundation is calling on the recycling industry to further focus on its role in alleviating the effects of climate change through championing the circular economy. The GRF strongly believes that recycling is both an integral and important part of the circular economy cycle and is an important contributor in supporting CO<sub>2</sub> reduction to meet climate change goals.

### **The link between recycling and climate change**

Recycling has been shown to lead to reduced carbon emissions and is paramount to the fight against climate change. Evidence from the Bureau of International Recycling has shown that recycling can save over 700 million tonnes in CO<sub>2</sub> emissions every year.

Recycling helps to tackle climate change and promote sustainable economic growth due to the fact that less energy is required in the manufacturing of products using recyclable raw materials, fewer materials are incinerated saving further carbon emissions and less waste is sent to landfills meaning a decrease in greenhouse gases released into the atmosphere.

These are some of the many reasons Global Recycling Day was launched in 2018, in order to encourage the world to think 'resource not waste' and look after the future of our planet. And, in order to live up to climate change agreements and reduce our collective carbon



footprint, the Global Recycling Foundation urges governments, organisations and individuals around the world to further invest and support the growth of recycling industries.

Global Recycling Day and awareness around recycling is key to making the changes we need to see. And while it's still a while away, we encourage everyone to gear up for Global Recycling Day 2020 and think about how they can get involved and support their planet – although action shouldn't be limited to just a day. The importance of recycling and its key benefits in lowering worldwide carbon emissions and reducing climate change is key to our future and should be remembered throughout the year. ■

### **Ranjit Baxi President**

Bureau of International Recycling (BIR)  
Founding President  
Global Recycling Foundation  
Tel: +32 2 627 57 70  
bir@bir.org  
www.bir.org  
www.twitter.com/BIRworld  
www.twitter.com/GlbRecyclingFdn

# The Europe Commission's priorities for the environment

Here, we focus on the European Commission's priorities for the environment, including water management and air pollution

**K**armenu Vella is the European Commissioner for Environment, Maritime Affairs and Fisheries in the European Commission. He was born and brought up in a fishing village in the South of Malta, relying heavily on the maritime economy. This gave him insight into the importance of the sea, for fishermen, the economy and sustaining the environment. He is, therefore, focused on blue growth, via a reworked Fisheries Policy that would allow rebuilding of the stocks of fish.

From 2014 until now, Karmenu Vella has been responsible for protecting the environment whilst encouraging Europe's competitiveness, and implementing the new Common Fisheries Policy. He further leads the charge to harness the potential of land and sea: both to create sustainable jobs, and to make sure those jobs preserve natural resources. He is a leader of managing and governing the planet's oceans, in association with the global partners of Europe.

He is involved with the Environmental Implementation Review (EIR), which is intended to help Member States apply EU environment rules.

On the 5th April 2019, the Commission published the second EIR. Within, there are 28 expected country reports showing stages of the implementation of EU environment law and highlighting gaps in implementation. Each Member State also receives recommendations, conclusions and knowledge of common trends at the EU level. The initiative was launched in 2016, to focus on realistic implementation of commonly agreed rules in all EU Member States. This implementation is crucial for environmental health - the laws and policies in existence are cohesive, but as Commissioner Vella believes, they need to be implemented as they were agreed. Member States have been given access to EIR

P2P PeertoPeer programme, which is established in 2017 to create and improve the shared knowledge of environmental authorities.

If the EIR is successful in its task, full implementation would mean that the EU economy saves roughly €55 billion every year. These costs are to do with health and more direct consequence costs done to the environment.

Karmenu Vella said: "The Juncker Commission is committed to building a Europe that protects. Making sure that the air, water and waste management our citizens enjoy are of best quality and our natural capital is protected is our priority."<sup>(1)</sup>

Waste prevention, water management and air pollution are key areas of implementation that Commissioner Vella believes in. The circular economy has been strengthened policy-wise, but waste management is a recurring obstacle for Member States. Nine countries are currently expected to attain their recycling goals for 2020, with five who already attained this achievement. However, 14 other States are unlikely to manage this goal by 2020. The relationship between efficient waste management and the circular economy is mutually beneficial, as they strengthen one another.

Water management is at a less developed state of completion: 2027 is the year for water bodies to achieve their goals, but in 2019, urban wastewater is not treated properly in two thirds of Member States. Whilst there are dialogues open on this matter, the real issue is that financial investment needs to be increased by Member States to make climate friendly urban wastewater management a reality. The EU says it remains committed, financially continuing to pursue implementation.





**“The Juncker Commission is committed to building a Europe that protects. Making sure that the air, water and waste management our citizens enjoy are of best quality and our natural capital is protected is our priority.”**

In relation to air pollution, the EIR reveals that 18 Member States are finding it difficult to lower their high levels of nitrogen oxide (NOx) emissions. A further 15 countries need to reduce their particulate matter emissions. Air pollution has multiple implications for health, which elevates the matter to an urgent priority for all Member States. Resultantly, the EIR was involved in the creation of clean air dialogues with several countries alongside a continued review of environmental policy implementation. The dialogue, therefore, created a necessary place to work out how to bring Member States to the same level, or to establish consistent progress. The EIR found that 62,300 premature deaths attributable to fine particulate matter concentrations occurred in Germany, whilst the United Kingdom showed no air quality improvements despite exceeding the limits for nitrogen dioxide. Further findings by the EIR confirmed that States were not decreasing their air pollution rates with appropriate speed.

Speaking in Brussels at a Biodiversity conference in May, Commissioner Vella said: “One planet is all we

have. It’s fragile and threatened, but fabulous too. Let’s channel that emotion, and ride on that wave. One planet – our treasure. Let’s give it hope – and the protection it needs.”<sup>(2)</sup>

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# Blowing in the wind: The complexities of understanding the consequences of air pollution on human health

Dr. Francisco Inesta-Vaquera, Dr. Colin Henderson, Professor Jonathan Grigg and Professor C. Roland Wolf from the Universities of Dundee and London discuss the complexities of understanding the consequences of air pollution on human health

Environmental pollution is recognised as a major risk for global health and is attributed to 7 million deaths a year. Exposure can be a consequence of industrial activity, the natural environment or urbanisation. Although the European Union (EU) and international agencies are acting to lower human exposure this will remain a major human health issue for many decades<sup>1</sup>.

Socioeconomic factors together with geographical location are major determinants of individual susceptibility to toxic pollutants and in spite of the overwhelming evidence of their harmful effects, the mechanisms which underlie the diseases which they induce or exacerbate are poorly understood. This can be partially attributed to the complexity of the chemical composition of pollutants which can vary temporally and be different between exposure areas (individual exposome)<sup>2</sup> and also, the difficulties in defining toxic mechanism where multiple compounds and particles are involved.

Within the general population, there are groups which are particularly susceptible to chemical/pollutant toxicity and where the consequences of exposure are most profound. Of particular importance but still only studied to a limited extent, are prenatal and post-

natal exposure. Exposure of pregnant women to pollution, particularly during the first trimester, is associated with lower infant head size during gestation and at birth, increased intra-uterine growth restriction and low birth weight<sup>3</sup>. The effects of intra-uterine exposure can extend into adulthood (and potentially trans-generationally) in the form of cancer or an impaired cognitive development<sup>4</sup>. Studies in experimental models, for example, using carcinogens, have clearly demonstrated that the toxicity and carcinogenicity are much more marked in the neonatal period<sup>5,6</sup>.

Moreover, children are especially vulnerable to air pollution as they breathe more air per unit of body weight and their organs are still developing. A further vulnerable group are individuals with pre-existing medical conditions such as respiratory, cardiovascular conditions or atopic dermatitis<sup>7-9</sup>. Vulnerable groups would also include individuals with a genetic predisposition to a disease or the deleterious effects of environmental agents<sup>10</sup>.

There remain numerous challenges in fully understanding the consequences of pollutant exposure. Epidemiological studies have demonstrated the association of both short- and long-term exposure to air pollution with an

increase in diseases aforementioned<sup>4</sup>. However, this is probably only the tip of the iceberg, as chemical components of polluted air are known to induce a wide range of toxic effects on cells, including inflammation (including cells of the immune system e.g., T-cells, macrophages), oxidative stress, DNA damage.<sup>11-13</sup>. There is an urgent need to increase research efforts to define toxic mechanisms and the specific agents involved.

Because of the complexity of this research, a multidisciplinary approach is needed involving both laboratory and human exposure studies. To assess the toxic potential of environmental pollutants the mechanisms of how these complex mixtures of compounds and particulate matter induce their deleterious effects needs to be established. The human studies to date have predominately relied on the measurement of markers of exposure in surrogate tissues and body fluids (i.e. blood, urine samples)<sup>14</sup>. Although this work has generated valuable insights into disease aetiology and to some degree mechanism there are many confounders which complicate the interpretation of epidemiological studies. These include variability between individuals, duration, level and composition of exposure and the transient nature of the experimental

endpoints being measured. Whereas such measurements may reflect levels of exposure, they do not provide definitive insights into toxic mechanism or indeed identify the target cells. Laboratory studies are needed for this purpose. It should be noted that some of these limitations can be obviated by controlled volunteer studies using exposure chambers but these studies are time-consuming, costly and restricted by ethical considerations.

*In vitro* studies using specific human cell types e.g. alveolar cells in culture have been valuable in gaining some mechanistic insights into the effects of air pollution<sup>15</sup>. However, these model systems lack the cellular complexity of the whole organism, for example, the interaction of target cells with the immune system.

Our knowledge of the response of cells to an environmental challenge has increased dramatically. A range of adaptive response systems have been identified which specifically protect cells from the deleterious effects of both endogenously produced and exogenous toxic agents. The activation of these pathways in a cell, therefore, not only reflects potential toxicity but also provides insight into toxic mechanism<sup>16</sup>. The measurement of these pathways is, therefore, a powerful approach to evaluate the toxic potential of both single and complex mixtures of pollutants. One attraction of using such generic adaptive stress responses as markers of toxicity is that they allow the comparison of the toxic potential of complex pollutant mixtures, for example, between different geographical regions of the world.

Measurement of these pathways *in vivo* allows the complexities of toxic mechanisms to be studied. Such studies can include different routes of administration and dosimetry.

Although the extrapolation of data using animal models to man continues to be debated, most chemicals which are toxic in man are also toxic in animals. Also, at the present time *in vivo* studies allow the complexities of environmental exposure to be established at a mechanistic level. Data resulting from such investigations can then be validated in human studies.

A number of transgenic lines have been created where oxidative stress, inflammation, DNA damage and AhR interactions can be measured *in vivo*<sup>17-18</sup>. This has facilitated ongoing mechanistic studies into the toxicity of diesel particle components. These models are also being used to investigate how environmental pollutants act both neonatally (for example, by trans-lactational transfer) or within the developing embryo.

Understanding how pollutants exert their toxic effects is complex and inevitably will only be resolved through collaborative programmes involving a combination of epidemiological/biomarker and laboratory-based studies. There are a number of key impediments to research progress. In the first instance, although a major health issue and one of public concern and high levels of publicity through the media, the investment in the EU for research in this area relative to other areas of medical research is minimal. Superimposed on this there has also been a general demise in centres of excellence in toxicology in Europe. This is a serious concern not only for environmental research but also in chemical safety assessment and in the development of new drugs.

## Key considerations for government

**1.** Remove exposure. This may reduce in Europe in the near future e.g. electrification of transport, exposure free

zone, the transition to coal-free power generation but probably not in many other areas of the world in the foreseeable future. **2.** Increase the level of investment in defining the deleterious components of the polluted and natural environment and support research into understanding how these agents affect the pathogenesis of human disease and develop risk assessment models. **3.** Create centres of excellence specifically dealing with this topic and toxicology in general. **4.** Understand the reason for the increased susceptibility in vulnerable groups, for example, socioeconomic status, pre/post-natal exposure and pre-existing medical conditions. **5.** A collaboration between basic scientists, medical doctors, exposure experts, epidemiologists and toxicologists is needed to address this extremely important issue.

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University  
of Dundee

**Professor C. Roland Wolf**  
**Professor of Molecular Pharmacology**  
c.r.wolf@dundee.ac.uk

**Dr. Francisco Inesta-Vaquera**  
**Dr. Colin J. Henderson**  
Systems Medicine, School of Medicine,  
University of Dundee  
Jacqui Wood Cancer Centre, Ninewells  
Hospital, Dundee, UK  
Tel: +44 (0)1382 383 133

**Professor Jonathan Grigg**  
**Professor of Paediatric Respiratory  
and Environmental Medicine**  
j.grigg@qmul.ac.uk  
Queen Mary University of London



# Taxing and spending: How greening the fiscal and financial systems can help address environmental crises

When it comes to taxing and spending, Dominic Hogg from Eunomia Research & Consulting shares his views on how greening the fiscal and financial systems can help address environmental crises

There is an environmental crisis unfolding. The word 'crisis' might sometimes be over-used, but here it really does reflect the scale of the problem confronting us. Alongside a climate crisis, we have plastic and air quality emergencies too: we're rendering species extinct by our activities and impacting on the health and wellbeing of our own in the process.

It's pretty obvious that we aren't taking these 'green issues' seriously enough. Nowhere is this more obvious than in the way our economies are organised. The most obvious example of this is the way in which – in the face of a climate emergency – politicians commit to phase out subsidies on the extraction and use of fossil fuels, but then fail to act on their 'commitment'.

When it comes to public finances, things don't look much better. Most countries seek to generate revenues through taxation, with the vast majority relying on taxes on income, labour, value-added, or profit to generate the income they need to fund state activities. None of these are especially deserving of having a tax slapped on them: the same can't be said for environmental pollutants, or activities that damage the environment, such as deforestation or building houses on a meadow. Surely the activities that generate such a wide range of environmental problems should be the ones that are taxed?

In 2017, total environmental tax revenue in the EU amounted to 2.4 % of EU GDP and 6.1 % of total EU government revenue. Taxes on energy accounted for more than three-quarters of the total revenues from environmental taxes and taxes on transport accounted for most of the balance, with taxes on pollution and resources amounting to 0.2% of all revenue from taxes and social contributions. Bluntly stated, that's ridiculous.

Now look to the world of finance. A large number of stakeholders worldwide, including banks, policy-makers, academia and NGOs, are engaged in defining what should be considered "green" in finance. The fact that this is only beginning to happen highlights both how slow the world of finance has been to recognise that the things it has been funding are largely destructive and the fact that the vast majority of this continues unimpeded by any corrective policy that seeks to reduce the harm caused.

If you think about how these things fit together – the tax system that lets polluters off the hook and the finance system that is beginning to define a portion of what it does as 'green' – then you start to realise why we're in the fix we are in.

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**"In 2017, total environmental tax revenue in the EU amounted to 2.4 % of EU GDP and 6.1 % of total EU government revenue. Taxes on energy accounted for more than three-quarters of the total revenues from environmental taxes and taxes on transport accounted for most of the balance, with taxes on pollution and resources amounting to 0.2% of all revenue from taxes and social contributions. Bluntly stated, that's ridiculous."**

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We are seeing a shift. Some citizens, policy-makers and financial backers are beginning to understand that money can support good projects as well as bad ones and that at its core, the question is: 'Do you want to support things that worsen an already dreadful situation, or contribute to improving it?' At the moment, however, we're still seeing investors framing the choice in terms of replacing things that were unequivocally 'bad' with things that are 'marginally less bad'. And if you are a citizen in the UK, just see what hoops you



need to jump through to ensure your pension fund isn't invested in fossil fuel assets. Even if you, as a citizen, really want to put your money where your green mouth is, you will have a job doing so. Consequently, the majority of the vast swathe of pension fund assets are still propping up an economy that's not just 'not green': it's completely colour-blind.

The task of greening the economy, therefore, is a work in progress. The falling cost of generating renewable energy shows what can happen when incentives start to align with the need to act. Carbon pricing helps to drive projects in renewables and to a lesser extent, energy efficiency. The financial models for such projects are also relatively easily replicable and transferable. What we now need is a step change in how we incentivise action in all the other areas where we face crises, thereby, sending signals to the finance community that decent returns on investment are no longer there for projects that harm the environment. Financial backers, in turn, need to become more creative in their project finance models and in how they value corporations. This will require us to identify and incentivise revenue streams derived not just from the sale of energy, but also, avoided expenditures – on health, or water

treatment - associated with all forms of environmental improvement.

Greening the economy requires this simultaneous shift in policy and finance. The two – setting incentives to shift the returns on investment and shifting investment to areas that are genuinely green – need to co-evolve. If they don't co-evolve swiftly, then we'll be facing a bleak future. At the same time, we largely understand the types of change we need and indeed, there are inspiring changes taking place across the world. The challenge, now, is to ensure their rapid diffusion and to stem the flow of funds towards those activities which simply worsen the existing crises. ■

**Dominic Hogg**  
**Chairman**

Eunomia Research & Consulting  
Tel: +44 (0)117 917 2250  
[dominic.hogg@eunomia.co.uk](mailto:dominic.hogg@eunomia.co.uk)  
[www.eunomia.co.uk](http://www.eunomia.co.uk)  
[www.twitter.com/@Dom\\_Hogg](https://twitter.com/@Dom_Hogg)

# Climate Emergency, solutions and the role of universities

Prof Dr Raimund Bleischwitz from UCL The Bartlett School of Environment Energy & Resources (BSEER) tells us about a new socio-political movement, which uses nonviolent resistance to protest against a potential climate breakdown and ecological collapse, and the transformational power of universities

The activists from Fridays for Future and Extinction Rebellion are widely recognised as a new socio-political movement, which uses nonviolent resistance to protest against a potential climate breakdown, biodiversity loss and the risks of human extinction and ecological collapse. We support their objectives and urge people and decision makers to act. Evidence from the research is overwhelming:

- The recent Global Environmental Outlook of the UN Environment Programme ([GEO6](#)) expects human health in dire straits unless action is taken; it establishes, for instance, that air pollution causes 7 million deaths annually and sudden-onset disasters have displaced 24.5 million people in 118 countries in 2016, three times more than conflict did.
- The Intergovernmental Panel on Climate Change ([IPCC](#)) has released a special report with a comparison between global warming of 1.5°C and 2°C above pre-industrial levels, pointing at risks of more hothouse days and higher sea level rise, more severe impacts on biodiversity and amplified exposure of islands and low-lying coastal areas.
- The [Lancet](#) Countdown tracks a range of indicators in health and climate change and impacts on labour

capacity, vector-borne diseases and food security, all with potential to disrupt core public infrastructures and services.

- Resource scarcity is on the rise, in particular, access to water, food and fertile land. The International Resource Panel ([IRP](#)) shows a responsibility gap, as the material footprint associated with high levels of consumption is thirteen times higher in rich countries compared to low-income groups.

## UCL is committed towards Grand Challenges

All those reports have been rigorously reviewed and represent a consensus across researchers worldwide. UCL is proud to support the delivery of those scientific signals and is committed to world-leading education and research to meet Grand Challenges. As alarming as it may sound, however, UCL research underlines feasibility and co-benefits of a range of strategies. Stringent actions can and should be taken now, such as:

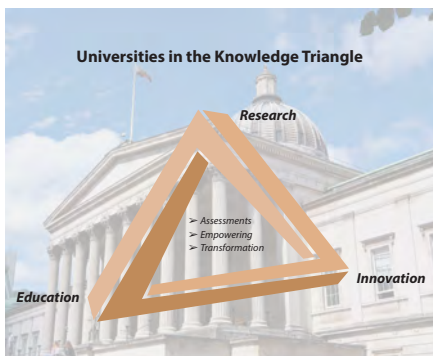
- Energy and [resource efficiency](#) in the manufacturing industry to save costs and enable sustainable investments adding \$2 trillion annually to the global economy;
- Solar-powered [irrigation](#) in Africa and other developing countries to

feed the malnourished people around the world and to produce 'more [crop](#) per drop';

- Switch from diesel and other combustion engines to [e-buses](#) and other forms of low carbon mobility in urban areas to clean the air. Mobility will be designed to become a service ([Maaslab](#)).
- Individual action matters too, such as using a bike, walking or sharing a car and drive less, adopting healthy food patterns and enjoying soft tourism.

The time window has been open since the international agreement (UNFCCC) was signed and ratified in the early nineties of the last century. Much has been delayed since due to lobbying, bad politics and behavioural inertia – yet, much can and should be done now and in the next years and decades. It is very important to keep the momentum and not to postpone action. The outcome of the European elections in May 2019 underlines the voice of the people pushing for climate action. What other agenda can be more relevant for our common future? [Young Europeans](#) want the Union to become a beacon of sustainability, a place that respects the rights and livelihoods of all its citizens and the environment. Smart and comprehensive strategies are needed, with





alignment towards the UN Sustainable Development Goals (SDGs), in areas of energy, housing and urban development, food and water. A circular economy will help to address interlinkages and creation of public values.

It is good to see the younger generation and civil society reclaiming space in the public debate and put pressure on decision makers. Some of their activities might be debatable or perhaps even considered illegal – yet, those who are denying the science of climate change and those who postpone climate action are to be criticised and have their share in creating anger and mistrust.

## The Transformers: Universities as catalysts of change

Universities have a role to play in the transformational changes ahead. Research is already driving evidence on integrated assessments and risks. It also helps to develop the solutions. The particular strength of universities transcends the wellsprings of fundamental research and application – fit for the 21st century, it stretches into understanding processes of change and identifying trigger points. The space of universities in innovation systems is no longer confined to patenting and publications, contemporary research analyses actors and institutions and recommends roadmaps into a better future. In line with findings from Judy

B. Rosener and Elaine P. Maimon on leadership, we underline skill development about systems thinking outside-the-box and creating new knowledge through collaboration and shared ownership. Universities become catalysts of change.

While a bachelor degree prepares students for a first job via strong foundations in critical thinking, problem-solving tools and communications, it is also clear that life-long learning and strategic thinking will be needed to shape the future towards the SDGs in all countries. Our world-class post-graduate programmes do just that:

The MSc in Sustainable Resources: Economics, Policy and Transitions (SRes) makes people experts in the areas of the circular economy, resource efficiency and sustainable resource management.

The MSc on Economics and Policy of Energy and the Environment (EPEE) equips future leaders with all relevant skills and knowledge about a low carbon development.

The MSc on Energy Systems and Data Analytics (ESDA) provides an academically leading and industrially relevant study of energy systems through the lens of data analytics.

Being located at the No. 1 faculty in the world on the built environment ('The Bartlett'), our other programmes enable students to become leaders in smart buildings and digital engineering (SBDE), Health, wellbeing and sustainable buildings (HWSB), Environmental design and engineering (EDE) and the challenges of sustainable heritage (ISH) and the data science for it (DSCH).

There is also a range of dedicated PhD programmes (such as a Centre for

Doctoral Training on energy resilience and the built environment, ERBE) and an increasing appetite to strengthen third-age learning and executive education – our ambition is to inspire and train leaders to move from business development into market-shaping transformations. All education programmes thrive on a rapid exchange with research, for example, on modelling, global low carbon shipping and on islands and are designed to co-produce knowledge with our partners from outside the university.

Research findings suggest a committed few can influence the majority and sweep away tyranny and social constraints. Erica Chenoweth and others explain the nonviolent overthrows of Boutefflika in Algeria and Bashir in Sudan by their "law of 2.5%": if such moderate share in a society decides to engage in civil disobedience, they attract others and trigger change. A little more of 25% is needed to move from experimental niches and upscale to a tipping point in social convention for unrelenting landslide changes.

No need to wait for a majority. No reason to become complacent. Get engaged and stay tuned.



### Prof Dr Raimund Bleischwitz

The Bartlett School of Environment,  
Energy & Resources (BSEER)

Tel: +44 (0)20 3108 9207

[r.bleischwitz@ucl.ac.uk](mailto:r.bleischwitz@ucl.ac.uk)

<https://www.ucl.ac.uk/bartlett/bartlett-school-environment-energy-and-resources>

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# Climate change: Science and scepticism

Peter Jansen – Principal Lecturer and sustainable business expert,  
London School of Business and Finance, explains the science behind climate change  
and the barriers preventing people and businesses from acting

In October 2018, the Intergovernmental Panel on Climate Change (IPCC), an inter-governmental body of the United Nations, published a report called “Global Warming of 1.5°C” (IPCC, 2018). The report reveals that human-induced activities have caused an average global warming of 1°C (+/- 0.2°C) above pre-industrial levels (1850-1900) and that the relentless consumption of fossil fuels is driving a warming of 0.2°C (+/- 0.1°C) per decade.

Moreover, in most scenarios, the world will not prevent a mean average global warming of 1.5°C in the next 20 years and 1.5°C levels could even be achieved as early as 2030 unless ambitious mitigation and climate adaptations towards sustainability are implemented (Levin, 2018). This further confirms the need for increased global collaboration regarding policy and mitigation to prevent global climate change which will drive increasing poverty, inequality and human suffering.

The primary greenhouse gases (GHG) driving global warming are carbon dioxide, water vapour, methane, ozone and nitrous oxide. While GHG are naturally existing gases, heightened levels of carbon dioxide (CO<sub>2</sub>) are directly connected with the use of high-carbon fossil fuels (IPCC, 2018).

Global warming was identified internationally as the cause for climate change during the 1930s and 1950s. However, it is not just global warming and high levels of greenhouse gases in the atmosphere that are the problem, there are also related impacts such as the melting of the polar ice caps and glaciers due to global warming causing sea-levels to rise and resulting in unprecedented structural damage and the displacement of millions of people living in low areas. Rising temperatures will also result in massive heat-related

migration from hot to cooler regions and natural weather systems will become more extreme (droughts, floods, hurricanes, etc). Finally, climate change effects will mainly affect vulnerable populations (IPCC, 2018).

When the potentially disastrous effects of climate change are so obvious, why do people and businesses fail to address this problem which threatens to undermine human civilisation? One reason is that the social and economic benefits of fossil fuels have long eclipsed the threat of global warming. However, the exponential global population growth is only increasing the demand for these resources. Gifford (2011) argues that inaction stems from both financial restrictions and psychological barriers, such as limited problem knowledge, ideological world views, distrust towards experts and authorities and perceived risks of change. Finally, several legitimate scientific counter-arguments to the IPCC reports have also created confusion regarding the reasons for and necessity of a transition to a low-carbon economy, as climate change and global warming are complex and multidimensional issues (Ringrose, 2018).

As stated by the IPCC (2018), sustainable development does not imply a return to pre-industrial times. It is a period of change and self-reflection which can strengthen both the economy and the wellbeing of society. The concept of sustainable economic development was first mentioned in the Brundtland Report (‘Our Common Future’, 1987) from the World Commission on Environment and Development.

Sustainable economic development “meets the needs of current generations without compromising the ability of future generations to meet their own needs” (WCED, 1987). This definition of sustainability involves two key premises that give some guidance: 1. Economic

activity should advocate social welfare and conserve natural resources and 2. Economic activity should consider impacts on future generations and manage natural resources in such a way that they remain productive for future generations (Sanders and Wood, 2015).

The idea that not only the government but also businesses share some responsibility for the environment and society at large really gained ground in the 1980s. Sustainability is not an abandoning of the traditional profit principle of business, on the contrary. The advantages of sustainability can be less pollution, healthy ecosystems, advanced public health and satisfied consumers, but the basic driver is company profit. Sustainability would fail if it did not lead to profit, instead, it only grew. Sustainability is of strategic importance for companies, not just for environmental reasons, but because it makes business sense (Sanders and Wood, 2015).

This idea is also supported by scientific research. Research shows that high-adopters of environmental management systems (EMS: ISO 14001) are more disposed to show reductions in air emissions, solid waste and energy consumption. It also identified financial benefits from EMS implementation, including increased operational efficiency, raw material and energy preservation, improved access to subsidies and lower insurance premiums. Other less tangible benefits include improved company reputation and risk minimisation (Sanders and Wood, 2015).

However, recent studies show that businesses are not prepared for fast changes in financial reporting regulation, let alone for the impacts climate change will have on their organisations. Messenger, Effendi and Pierce (2017) in a multi-country and multi-sector study concluded that companies are reluctant to embrace new low-carbon technologies because they are afraid they might lose out if their competitors don't follow them. They also found a huge global disparity in terms of preparedness and a positive correlation between markets that have existing regulation (e.g. the European Union) and compliance or preparedness, although this may change rapidly due to a changing public opinion (Extinction Rebellion!) and investors and regulators increasingly demanding climate-related financial disclosures.

Business leaders from around the world agree that sustainable business development is key to remaining competitive. Much can be achieved with the existing technology but there is still a long way to go. New carbon regulations are about to come online at an increased rate and with increasing international reach, as trading partners and blocks are looking for new ways to strengthen and develop the impact of their existing policies (World Bank and Ecofys, 2018). The tipping point has been reached and more and more people and businesses start to take climate change seriously and are willing to act in order to prevent future generations from taking the brunt. ■

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**Peter Jansen**

**Principal Lecturer and Sustainable Business Expert**

London School of Business and Finance

Tel: +44 (0)20 3535 1122

[info@lsbf.org.uk](mailto:info@lsbf.org.uk)

[www.lsbf.org.uk](http://www.lsbf.org.uk)

[www.twitter.com/lsbf](https://twitter.com/lsbf)



# Climate Service Center Germany (GERICS) goes for Nature-Based Solutions

Climate Service Center Germany (GERICS) contributes to increasing the evidence base on Nature-Based Solutions by taking part in two Horizon 2020 projects, NAIAD and OPERANDUM, as we find out here

Climate change, as well as ongoing environmental degradation, are exacerbating societal challenges, such as water and food security, poverty, or human health. At the same time, society is becoming increasingly aware of the value of nature in supporting human well-being. These facts boosted the development of new approaches which highlight the role of natural processes for tackling socio-environmental challenges. One of these approaches is the concept of Nature-Based Solutions – NBS. Nature-Based Solutions are solutions to societal challenges that are inspired and supported by nature (Raymond et al, 2017). According to many definitions of Nature-Based Solutions, a common goal of their application is to find a balance between social, environmental, economic objectives and even long-term sustainability.

The creation of floodplains is an exemplary Nature-Based Solution. By giving more space to a river at targeted points, water levels at vulnerable points are less high. An alternative conventional so-called grey measure is to raise dykes for flood protection. In respect to the social challenge of optimal water quality and food security, adopting agricultural practices, such as crop rotation can improve water infiltration, as well as increase the harvest.

Nature-Based Solutions often draw on

traditional, well-established practices. Further, the ability to address societal challenges in a variety of ways and to comprise co-benefits is nature of Nature-Based Solutions. This is an advantage of Nature-Based Solutions over many conventional approaches. The concept is progressively gaining importance in the European Union policy agenda. Nature-Based Solutions are an innovative way of adapting to environmental change, shifting to a greener economy and a more sustainable society and even creating new jobs. However, evidence on the cost-effectiveness of Nature-Based Solutions in the long-term is still scarce. For this reason, the European Commission is investing in a series of projects aiming to strengthen the evidence base on Nature-Based Solutions in the context of its Horizon 2020 Framework Programme. The Climate Service Center Germany (GERICS) is currently taking part in two of these projects, NAIAD (Nature Insurance value: Assessment and Demonstration) and OPERANDUM (OPEN-air laboratories for Nature based solutions to reduce hydro-meteorological risks).

NAIAD aims to internalise the insurance value of ecosystems in risk management practice and agendas. The assumption is that Nature-Based Solutions can reduce the vulnerability to climate-induced hazards, especially droughts and flooding. The resulting risk reduction can be assessed and

incorporated within insurance schemes. NAIAD aims to develop concrete Nature-Based Solutions at nine demo sites across Europe focusing on droughts and floods within catchments in a source to sea continuum. The NAIAD project partners develop and test – with key insurers and municipalities – the concepts, tools, applications and necessary instruments for mainstreaming Nature-Based Solutions.

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**“The creation of floodplains is an exemplary Nature-Based Solution. By giving more space to a river at targeted points, water levels at vulnerable points are less high. An alternative conventional so-called grey measure is to raise dykes for flood protection.”**

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In order to enable the interactive exchange of information, GERICS applies an integrative participative modelling approach within NAIAD. It considers the needs of local stakeholders from the fields of insurance, nature conservation and regional planners, as well as the approaches of interdisciplinary groups from the natural and social sciences. Participative processes and group modelling techniques are the basis for the development of quantitative system dynamic models. These system dynamic models combine physical, socio-economic, as well as climate data and allow to model the socio-economic consequences of the implementation of Nature-Based Solutions. System

dynamic models help to improve the understanding of systemic processes and, therefore, support decision-makers in their actions.

The second project, GERICS is involved, is OPERANDUM. This project aims to deliver tools and methodologies for the validation of Nature-Based Solutions in order to enhance resilience in European rural and natural territories by reducing hydro-meteorological risks. One of the objectives is to provide science-evidence for the usability of Nature-Based Solutions and best practices for their design, based on participatory processes. Therefore, the project expands the concept of Living Labs to a broader vision for natural and rural areas. In seven European countries and a further three in China and Australia, Nature-Based Solutions for coping with hydro-meteorological risks are being developed and implemented in so-called open-air laboratories. Assessing the effectiveness of these Nature-Based Solutions through innovative monitoring systems and state-of-the-art numerical modelling approaches is a further objective in OPERANDUM.

GERICS is involved in the German open-air laboratory, which is represented by the biosphere reserve "Niedersächsische Elbtalaue", close to Hamburg. Flood protection is of great importance in the biosphere reserve. A Nature-Based Solution to cope with flood risks is nature-based floodplain management. GERICS investigates different Nature-Based Solutions for this region with regards to their local transferability and efficiency under changed climatic conditions.

To ensure a sustainable and long-term efficiency of the Nature-Based Solutions for all open-air laboratories, GERICS supports the co-design development of Nature-Based Solutions with the provision of user-oriented processed regional climate information.

**"In respect to the social challenge of optimal water quality and food security, adopting agricultural practices, such as crop rotation can improve water infiltration, as well as increase the harvest."**

Nature-Based Solutions is still a concept that needs more acceptance at the global governance level, as well as at the landscape planning level in rural and urban areas. Both projects aim to improve the acceptance of Nature-Based Solutions by integrating knowledge about the Nature-Based Solutions efficacy against hydro-meteorological risks. There is no single Nature-Based Solution addressing all challenges. Each time a solution needs to be designed to address the relevant challenges in its local context and its respective community.

For the design of Nature-Based Solutions, an understanding of site conditions, including local information about future climate changes, is essential. To improve the understanding of the local systemic processes, GERICS applies a participative modelling approach. GERICS also facilitates to appropriately account for climate change information by providing science-based and user-tailored processed climate change information for local to regional scale of Nature-Based Solutions. With these

approaches, GERICS helps to ensure the long-term efficiency of Nature-Based Solutions and contributes to increasing the evidence base on Nature-Based Solution.

## Authors and Contact (alphabetic order)

Juliane El Zohbi ([juliane.el\\_zohbi@hzg.de](mailto:juliane.el_zohbi@hzg.de))

Eulalia Gomez ([eulalia.gomez@hzg.de](mailto:eulalia.gomez@hzg.de))

Swantje Preuschmann ([swantje.preuschmann@hzg.de](mailto:swantje.preuschmann@hzg.de))

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**Prof Dr Daniela Jacob**

Climate Service Center Germany (GERICS)

[daniela.jacob@hzg.de](mailto:daniela.jacob@hzg.de)

[www.climate-service-center.de](http://www.climate-service-center.de)

# An introduction to earthquakes in the U.S.

The U.S. Geological Survey (USGS) introduces what an earthquake is and what causes them to happen, plus the depth at which they occur

An earthquake is caused by a sudden slip on a fault. The tectonic plates are always slowly moving, but they get stuck at their edges due to friction. When the stress on the edge overcomes the friction, there is an earthquake that releases energy in waves that travel through the earth's crust and cause the shaking that we feel.

In California, there are two plates – the Pacific Plate and the North American Plate. The Pacific Plate consists of most of the Pacific Ocean floor and the California Coastline. The North American Plate comprises most of the North American Continent and parts of the Atlantic Ocean floor. The primary boundary between these two plates is the San Andreas Fault. The San Andreas Fault is more than 650 miles long and extends to depths of at least 10 miles. Many other smaller faults like the Hayward (Northern California) and the San Jacinto (Southern California) branch from and join the San Andreas Fault Zone.

The Pacific Plate grinds northwestward past the North American Plate at a rate of about two inches per year. Parts of the San Andreas Fault system adapt to this movement by constant “creep” resulting in many tiny shocks and a few moderate earth tremors. In other areas where creep is not constant, strain can build up for hundreds of years, producing great earthquakes when it finally releases.

## **At what depth do earthquakes occur? What is the significance of the depth?**

Earthquakes occur in the crust or upper mantle, which ranges from the earth's surface to about 800 kilometres deep (about 500 miles).

The strength of shaking from an earthquake diminishes with increasing distance from the earthquake's source,

so the strength of shaking at the surface from an earthquake that occurs at 500 km deep is considerably less than if the same earthquake had occurred at 20 km depth.

Also, the depths of earthquakes give us important information about the Earth's structure and the tectonic setting where the earthquakes are occurring. The most prominent example of this is in subduction zones, where plates are colliding and one plate is being subducted beneath another. By carefully plotting the location and depth of earthquakes associated with a subduction zone, we can see details of the zone's structure, such as how steeply it is dipping and if the down-going plate is planar or is bending. These details are important because they give us insight into the mechanics and characteristics of the deformation in the subduction zone.

The deepest earthquakes occur within the core of subducting slabs – oceanic plates that descend into the Earth's mantle from convergent plate boundaries, where a dense oceanic plate collides with a less dense continental plate and the former sinks beneath the latter. The plate boundary contact between two such plates generates very large, shallow subduction zone earthquakes such as the Sumatra 2004 M9.1 event and the 2011 M9.0 Japan earthquake and is only active to relatively shallow depths – approximately 60 km. However, because oceanic slabs are relatively cold with respect to the surrounding mantle in deeper subduction zone environments, faults within the core of these slabs remain brittle and can generate earthquakes to depths of as much as 700 km (e.g., Pacific Plate beneath Japan and Kamchatka and beneath Tonga).

As the slab descends into the mantle, rheology changes (viscosity characteristics) cause the plate to bend and



deform and generates these earthquakes. The trend of such events can be seen in cross-sections of subduction zones and are known as “[Wadati-Benioff Zones](#)”.

Within continents and along continental plate boundary transform faults such as the San Andreas, faults are only active in the shallow crust – perhaps to depths of approximately 20 km.

Accurately determining the depth of an earthquake is typically more challenging than determining its location, unless there happens to be a seismic station close and above the epicentre. So generally, errors on depth determinations are somewhat greater than on location determinations.

## **Are earthquakes associated with variations in the geomagnetic field?**

Electromagnetic variations have been observed after earthquakes, but despite decades of work, there is no convincing evidence of electromagnetic precursors to earthquakes. It is worth acknowledging that geophysicists would actually love to demonstrate the reality of such precursors, especially if they could be used for reliably predicting earthquakes!

*Learn more: [USGS Geomagnetism Program](#)*

## **How is hydraulic fracturing related to earthquakes and tremors?**

Reports of hydraulic fracturing causing felt earthquakes are extremely rare. However, wastewater produced by wells that were hydraulically fractured can cause “induced” earthquakes when it is injected into deep wastewater wells.

Wastewater disposal wells operate for longer durations and inject much more fluid than the hydraulic fracturing operations. Wastewater injection can raise pressure levels in the rock formation over much longer periods of time and over larger areas than hydraulic fracturing does. Hence, wastewater injection is much more likely to induce earthquakes than hydraulic fracturing.

Most wastewater injection wells are not associated with felt earthquakes. A combination of many factors is necessary for injection to induce felt earthquakes.

*Learn more at the [USGS Induced Earthquakes website](#)*

## **Do earthquakes large enough to collapse buildings and roads accompany volcanic eruptions?**

Not usually. Earthquakes associated with eruptions rarely exceed magnitude 5 and these moderate earthquakes are not big enough to destroy buildings and roads.

The largest earthquakes at Mount St. Helens in 1980 were magnitude 5, large enough to sway trees and damage buildings, but not destroy them. During the huge eruption of Mount Pinatubo in the Philippines in 1991, dozens of light to moderate earthquakes (magnitude 3 to 5) were felt by several hundred thousand people. Many houses collapsed, but not primarily because of the shaking. Heavy ash from the eruption (made heavier by rain from a hurricane) accumulated on roofs and crushed them.

Stronger earthquakes sometimes DO occur near volcanoes as a result of tectonic faulting. For example, four magnitude 6 earthquakes struck Long Valley caldera, California, in 1980 and a magnitude 7.2 earthquake struck Kilauea Volcano, Hawaii, in 1975. Both volcanoes were quiet at the time. The Hawaii earthquake triggered a small eruption at the summit of Kilauea. No eruption occurred at Long Valley. ■

*Learn more about how the USGS monitors volcano seismicity*

Earthquake and Geologic Hazards  
U.S. Geological Survey (USGS)  
Tel: +1 703 648 6786  
[wleith@usgs.gov](mailto:wleith@usgs.gov)  
[www.usgs.gov](http://www.usgs.gov)  
[www.twitter.com/usgs](https://www.twitter.com/usgs)

# A new turn in the search for the origin of life

Professor Friedemann Freund, SETI Institute, explores a fascinating new discovery in the search for the origin of life, here

Sometime in the distant past, life appeared on planet Earth. Nobody knows when, but it must have been at least 3.5 billion years ago, maybe 3.8 billion or even 4.3 billion years ago, relatively soon after Earth accreted in the disk of gas, dust and planetesimals that circled the early sun.

If there is much uncertainty about the timing of the origin of life, how life actually started is even more uncertain. A *sine qua non* condition for life as we know it is that, somewhere on the early Earth, blobs of organic molecules must have come together to form a “system” that could copy itself and multiply. No easy task, requiring large, complex molecules made of carbon, hydrogen and oxygen with some nitrogen and sulphur thrown into the mix. Using the chemical symbols of these elements we may call them CHONS.

The challenge is to understand how Nature could have produced the large, complex CHONS, without which the first self-replicating systems could never have formed out of the chaos of the pre-biotic Earth. Those CHONS must have contained hydroxy, carboxy, amino and sulphur functional groups. They must have been able to build vesicles with cell membranes. The vesicles must have had cell membranes pitted with cross-membrane functional groups that allowed protons and ions to flow in and out in such a way as to generate concentra-



tion gradients and transmembrane potentials – a form of energy.

Unfortunately, the science community has not yet figured out how Nature might have produced the large CHONS that were surely necessary to form such protocells and to give life a shot at getting started. Smaller organic molecules? No problem. Amino acids are easy to make, for instance by electric discharges simulating lightning strikes on the early Earth. The real challenge is how Nature was able to build much larger multifunctional CHONS.

For decades, the search was on to demonstrate how such CHONS could be assembled under plausible early-Earth conditions, in the atmosphere, in freshwater or the oceans, with help from ultraviolet light or high energy x-rays and gamma rays, at high and low temperatures, at high and low

pressures. Despite all efforts the goal remained elusive. The science community started to look elsewhere.

One idea that became widely accepted is that the young Earth had been intensely bombarded by the most primitive meteorites, carbonaceous chondrites, which may have accreted in the interstellar dust clouds, from which the entire solar system formed. We can see these dust clouds in the night sky forming dark bands in the luminous plane of our Milky Way galaxy.

The nano-sized mineral grains in the dust clouds bear the spectroscopic signature of delicate hydrocarbons and, indeed, carbonaceous chondrites that have fallen to Earth in recent decades were found to be amazingly rich in CHONS, including some that form vesicles when extracted with water and others that

contain carboxy, amino, and sulphur functional groups. Such CHONS would have come handy on the early Earth and they could have provided a path towards life. So, there it is – the idea that life on Earth owes its existence to organics delivered from space more than 4 billion years ago. A grand idea, quoted in the scientific literature and widely popularised.

However, when we drill down to its roots, we see that this idea came out the disappointment in the science community that, using the most advanced methods of investigation, some of the best minds in chemistry, physics, geoscience and astrobiology have not been able – despite decades of intense work – to figure out how Nature could have produced these large, complex and multifunctional CHONS, without which life as we know it could not have started.

As so often in the history of the human mind, in times of uncertainty, the imagination may turn to the even greater unknowns. This seems to have happened in the face of widespread frustration over the inability to make real progress in the area of origin of life. In this case, the imagination turned to space.

Maybe out there, in the vast expanse of space, chemical reactions are possible that have no equivalent on Earth. Maybe, when stars reach the end of their life cycle and die in cataclysmic explosions, the mineral grains condensing in the hot stellar outflows are uniquely able to produce those complex CHONS.

Maybe the organics associated with the dust clouds in the interstellar medium are such CHONS. Maybe they became incorporated into the carbonaceous chondrites, those pitch-

black, organics-rich clumps of very fine-grained matrix, probably formed in these humongous dust clouds in the galactic plane. Maybe the early Earth did indeed capture many of these carbonaceous chondrites and was seeded with the CHONS, from which life would eventually arise.

Posing the question in this way exposes a flaw in the basic approach taken by so many bright chemists, physicists, geoscientists and astrobiologists, whose goal is to unravel the mystery of the origin of life. For decades their focus has been on chemical reactions that take place in the gas, liquid and fluid phases, including supercritical conditions, at gas-fluid, gas-solid and fluid-solid interfaces, even inside clay minerals.

The condensation of mineral grains in the near-vacuum of space, in the outflow of dying stars, is a distinctly different process. It is the transition from the vapour phase directly to the solid state in the presence of hydrogen, carbon monoxide, water, nitrogen and sulphur. During the process, the gaseous components become incorporated into the solid matrix. The smaller the grains, the more of the gaseous components go in. Once inside, the C, H, O, N and S interact with each other, forming chemical bonds – a step towards CHONS.

Here is where past research to unravel the mystery of the origin of life went astray. Brilliant and dedicated as they were, the scientists involved in this field never considered the possibility that the reactive gases dissolved in the magmas in the depth of Earth – water, carbon monoxide and dioxide, even nitrogen and sulphur – would become incorporated into every mineral grain that crystallizes out of terrestrial magmas. Not in high concentrations

but at non-zero levels, nonetheless. During cooling, the C, H, O, N and S inside the solid matrix interact with each other and form chemical bonds – a step towards CHONS.

Therefore, there is no need to look to space and to carbonaceous chondrites to deliver CHONS to the Earth, precious organics from which life might have arisen. There is no need to worry that any such delivery could have happened only during the period of heavy bombardment of the young Earth more than 4 billion years ago. Quite to the contrary, there is the distinct alternative that rocks in the Earth's crust were producing CHONS inside the matrix of their minerals, releasing them as they weathered at the Earth's surface.

Even if the amounts of CHONS per unit volume of rock were very small, billions of cubic kilometres of rocks have weathered over the eons. In the accumulative, they must have injected huge quantities of CHONS into the Earth's surface environment. There was no shortage of potentially life-giving and life-sustaining organics.



**Friedemann Freund**  
**Professor**

SETI Institute/NASA Ames Research Center  
Tel: +1 650 279 8478  
friedemann.t.freund@nasa.gov



# The fight against climate change: We all foot the bill for a warmer Arctic

Joseph Cook, Vice President of the UK Polar Network (UKPN) Committee argues that we all foot the bill for a warmer Arctic in the fight against climate change

2019 is shaping up to be a watershed year in the fight against climate change. Coordinated international school strikes – whose figurehead Greta Thunberg has already been nominated for a Nobel Prize – and national movements such as the Extinction Rebellion have highlighted the urgent need for climate action. Major “scientainment” programmes such as the BBC’s “Climate Change: The Facts” and Netflix’s “One Planet” demonstrate that climate consciousness is rapidly becoming mainstream. The Governor of the Bank of England, Mark Carney, has recently made the economic dangers of climate change clear to bankers, warning the City to “take climate change seriously or lose money”, indicating that the message is finally permeating into influential institutions. Nevertheless, in a system where several degrees of warming are already “baked-in”, policy still severely lags environmental urgency and governments are distracted by various national crises, it remains to be seen whether this positive rhetoric translates into meaningful action and whether it does so rapidly enough to mitigate the worst effects of future climate change.

Immediate, meaningful action is critical to avoid further exacerbating the social, economic and environmental stresses that we will now inevitably face as our climate warms. While we often report climate change in terms of global averages, the effects of climate warming are felt more strongly in some places than others. The Arctic, in particular, is warming at more than twice the global average rate because the sensitive sea ice, glaciers and snow that cover large parts of the Arctic amplify warming trends. This happens because snow and ice are highly reflective and act like a mirror bouncing solar energy back into space. When temperatures rise that snow and ice become less reflective and when it melts away completely, it reveals dark land or ocean. This makes the planet less reflec-

tive, meaning more heat is available for warming the Earth. The effects of this are felt acutely in the Arctic but also ripple through global weather systems, economies, infrastructures and human societies. The Arctic is a sensitive victim of climatic change but at the same time a powerful accelerator of climate impacts worldwide, meaning we all pay the price for a warmer Arctic.

The Arctic is where most of the ice and snow in the northern hemisphere are concentrated. It is where most of our glaciers rest in mountain valleys and where the continent-sized Greenland Ice Sheet sits high atop the ancient continental crust. Both the glaciers and the ice sheet are shrinking, losing billions of tonnes of ice each year due to warming temperatures. This is a major issue because it adds water to the oceans, rising sea levels. This is not a localised problem.

Higher sea levels mean coastal areas and flood plains becoming uninhabitable, increased coastal and riverbank erosion, loss of land for agriculture, housing, utilities and businesses as well as storm surges that penetrate further inland causing more damage. It has been estimated that sea level rise alone could wipe \$14 trillion from the global economy every year by the year 2100 if we continue on our current rate of carbon emission (Jevrejeva et al. 2014). It has recently been estimated that by the end of the century Arctic warming will contribute \$66.9 trillion to the global economic costs of climate change under emissions scenarios expected under current national pledges (Yumashev et al. 2019). Almost four million people live in the Arctic region with cultures, traditions and livelihoods finely tuned to the cold environment that are threatened by climate warming. At the same time, warmer temperatures provide some opportunities, for example, retreating glaciers, ice caps and ice sheets will enable access



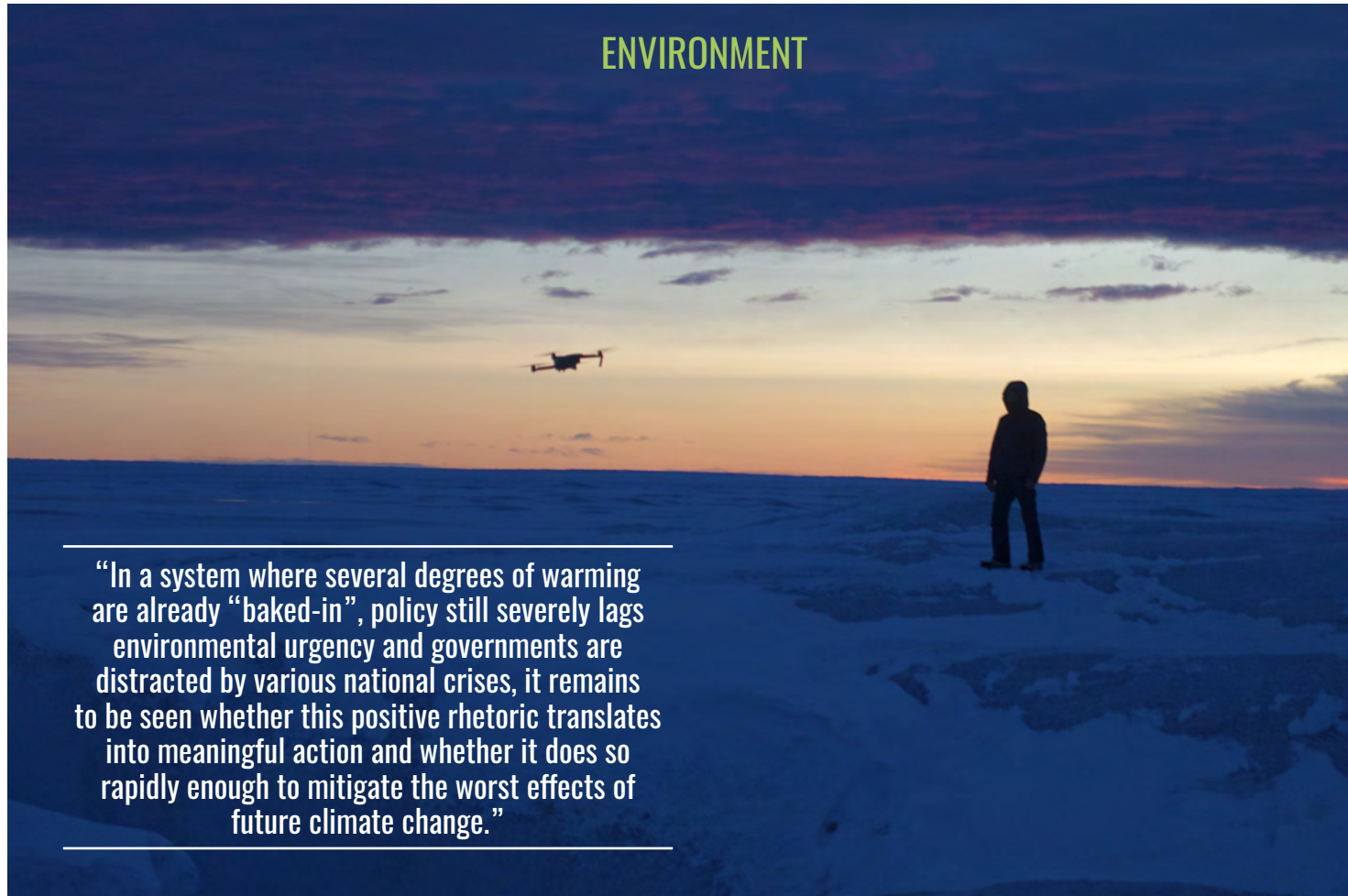
to new areas for mineral, oil and gas prospecting and new shipping routes. However, while beneficial for local economies, extracting these resources will be environmentally damaging and exacerbate a global climate crisis, raising sensitive geopolitical issues.

Changes to Arctic ice influence the weather locally and at lower latitudes, including over major population centres in northern Europe and North America. Because ice is cold, it influences the pressure of air masses above it, controlling the shape, position and strength of the jetstream and polar vortex. Extreme weather events will continue to increase in frequency and magnitude as the Arctic ice continues to retreat, exacerbating both floods and droughts and associated phenomena, such as wildfires and landslides, with the inevitable loss of life and damage to homes, businesses and infrastructures. This is not only happening in distant, uninhabited Arctic icescape but it is already happening to all of us, the world over. Even those who do not directly suffer the direct impacts of these environmental hazards will suffer through rising costs of insurance, living costs and a weaker global economy.

The ecological costs of a warming Arctic are also high, with indigenous, cold-adapted species pushed ever

closer to extinction by a rapidly changing environment and a northwards shift of invasive species. Grizzly bears have been observed migrating north into areas previously occupied only by polar bears and Arctic foxes. A further ecological cost is that cold oceans acidify more rapidly than warmer ones, threatening marine wildlife, especially those species that rely upon low acidity, carbonate-rich water for building shells. The rapidly declining Arctic sea ice is fundamental to the survival of seal and polar bear. Furthermore, as the polar bear habitat shrinks, these animals are forced into more frequent human contact. Melting glaciers are also releasing contaminants into rivers, oceans, lakes and soils to be taken up by plants and consumed by animals, concentrating up the food chain meaning amplified doses are ultimately consumed by humans.

Arctic warming costs us all dearly. The Arctic itself is a threatened landscape, sensitive and vulnerable to the stresses we place upon it by burning fossil fuels. Strong connections exist between the Arctic and the lower latitudes. Through temperature rise, the Arctic is vulnerable to distant carbon emissions, but at the same time, humans at lower latitudes are vulnerable to environmental hazards amplified in the Arctic. These strong mutual connections mean protection and stewardship




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“In a system where several degrees of warming are already “baked-in”, policy still severely lags environmental urgency and governments are distracted by various national crises, it remains to be seen whether this positive rhetoric translates into meaningful action and whether it does so rapidly enough to mitigate the worst effects of future climate change.”

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of the threatened Arctic begins with environmentally responsible behaviour at home. The costs of a warming Arctic are financial, humanitarian and ecological and are borne by everyone on the planet. Costs will increase as temperatures continue to rise. There must be a global movement towards leaving fossil fuels underground and relying upon renewable energy, while also generating less waste and adopting climate-conscious behaviours. There are still uncertainties in the feedbacks amplifying Arctic warming and the sensitivity of glaciers and ice sheets to climatic change that must be addressed as a matter of urgency. Understanding and monitoring how the Arctic is changing is key to accurately forecasting the timescales of change enabling proper management and mitigation measures to be put in place in a timely fashion. Because of the fundamental importance of Arctic processes to human societies globally, Arctic research must remain an international priority. ■

Joseph Cook is a postdoctoral researcher that has been studying albedo feedbacks on glaciers and ice sheets for over a decade. He is vice-president of the UK Polar Network and director of the polar science communication organisation “Ice Alive”. He is supported by National Geographic and Microsoft through the AI for Earth program. More information about his work can be found at <http://tothepoles.wordpress.com> and

[www.icealive.org](http://www.icealive.org) or @tothepoles on Twitter/Instagram. More information about the UK Polar Network is available at [www.polarnetwork.org](http://www.polarnetwork.org).

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## Joseph Cook Postdoctoral Researcher

University of Sheffield, UK  
Vice President of the UK Polar Network (UKPN) Committee  
[joe.cook@sheffield.ac.uk](mailto:joe.cook@sheffield.ac.uk)  
[tothepoles.wordpress.com](http://tothepoles.wordpress.com)  
[www.twitter.com/tothepoles](http://www.twitter.com/tothepoles)





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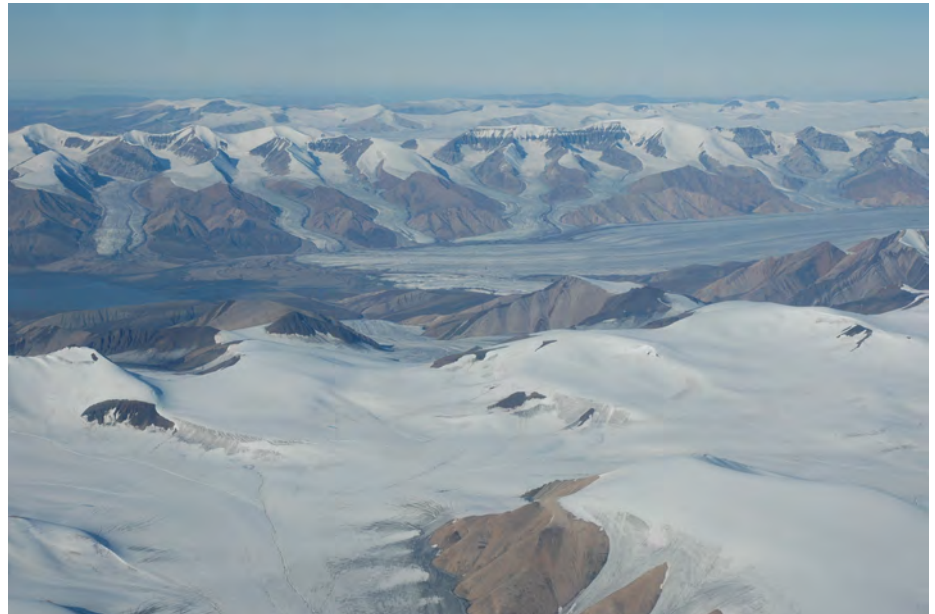
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# Ways to characterise how ice caps and glaciers change

Martin Sharp, Professor at Department of Earth and Atmospheric Sciences, University of Alberta, explains ways to characterise how ice caps and glaciers change

There are several ways to characterise how ice caps and glaciers change. Early work emphasised changes in glacier length derived from repeat measurements of the position of a glacier's terminus at a specific time of year (such as the end of the summer melt season). Note that numerous distinct glaciers may drain, in different directions, from a single ice cap and that these may not all change over time in the same way. Records of year-to-year changes in the annual maximum extent of a given glacier allow the identification of periods of advance, when the glacier terminus moves down-valley over time because the transport of ice to the terminus by flow exceeds the loss of ice there by melting and periods of retreat, when it moves up-valley because ice is removed more rapidly by melting than it is transported towards the terminus by glacier flow. Periods of glacier advance are generally regarded as an indicator of a glacier in good health, while periods of retreat indicate poor health.

Past periods of glacier advance and retreat can be identified by comparing positions of the glacier terminus in historical landscape paintings, terrestrial or aerial photographs, or satellite images that date from different points in time. The limits of past glacier advances are often marked by "end moraines" – ridges of sediment deposited or pushed up by the glacier during those advances. The timing of



the advances can be determined from documentary or graphical sources, or by direct dating of either the moraine surfaces, or of organic materials (such as plant remains, soils, peat layers, or tree stumps) that were overrun by the advancing glacier. Knowledge of the timing and rate of glacier changes allows assessment of whether and how they may be linked to past climate changes.

As the Earth's climate warms, we are increasingly concerned about how glacier change will affect the amount and timing of meltwater runoff passing through downstream rivers and lakes and about how glacial melting will impact global mean sea level. To address these two issues, we must quantify past and present changes in the mass of water being exported from glaciers. This requires that we

know how the mass of glaciers is changing over time.

To calculate the mass loss from a given glacier over a specific time period, we need to determine how the glacier's thickness and/or volume changed over that period. Historically, this was done in the field by measuring the annual "surface mass balance" of a glacier. This is the difference between the annual addition of mass to the glacier by snowfall during the winter "accumulation" season and the annual removal of mass from the glacier by melting of surface snow and ice during the summer "ablation" (or melt) season. If the annual addition of mass by snowfall exceeds the annual removal by melting, the glacier will grow over time. If mass removal exceeds mass addition, however, it will shrink. Mass removal occurs mainly



by surface melting and meltwater runoff to the ocean. The cumulation of the successive annual mass balances of a given glacier or ice cap over time provides an estimate of the overall changes in the glacier's mass over that period.

Where a glacier terminates in the ocean or in a proglacial or ice-marginal lake, mass loss also occurs by melting of the glacier's terminal ice cliff using heat derived from either the atmosphere (for ice above the sea/lake level) or the ocean/lake (for ice below the sea/lake level). Since glaciers are heated from below by geothermal heat, melting can also occur at the base of the glacier. Rates are typically low relative to surface melt rates, except when the glaciers are on active volcanoes (as are some in Iceland, for instance).

Iceberg calving removes ice from the terminal and marginal ice cliffs of glaciers. It is referred to as "dry calving" if the ice margin is on land and "wet calving" if the bergs are released into a lake or the ocean. For "tidewater" glaciers, which are in direct contact

with the ocean, the rate of mass loss into the ocean is affected by variables like the water depth at the glacier terminus (which determines whether the terminus is grounded on bedrock or floating), the water temperature relative to that of the ice (which affects the energy available for melting where ice and water are in contact) and whether there is active meltwater outflow beneath floating sections of the glacier terminus. This outflow might entrain warmer lake or ocean water as it rises through the water column and brings it into contact with the floating ice, thereby accelerating the melting of that ice. Whilst a cover of floating sea ice or lake ice on any water body in front of the glacier terminus may buttress the glacier's flow and limit the rate at which it loses mass by iceberg calving, the break-up and/or melting of such ice may trigger glacier advance and iceberg calving.

To study how glacier change affects global mean sea level or regional water resources, we must quantify changes in the mass of the entire population of glaciers and ice caps in the region of interest. To do this, we

use airborne or satellite remote sensing methods such as laser or radar altimetry, or satellite gravimetry. With altimetry, repeat measurements of the surface elevations of glaciers in a specific region are used to estimate the change in regional ice volume over time. Converting this volume change to an estimate of ice mass change involves multiplying the volume change by appropriate densities for the snow and/or ice that were added to, or removed from, the glaciers. With gravimetry, we determine changes in the mass of ice in a specific region from measurements of the perturbations in Earth's gravitational potential that are caused by the redistribution of mass that results from the melting of land ice and transfer of the resulting water to the ocean (or, if the mass of land ice is increasing over time, from the accumulation of snow on the ice cap or glacier). With this method, we are effectively using repeat measurements of the weight of the glaciers and ice caps in a region to document changes in ice mass over time.



**Martin Sharp**

**Professor**

Department of Earth and

Atmospheric Sciences

University of Alberta, Canada

Tel: +1 780 492 8546

[msharp@ualberta.ca](mailto:msharp@ualberta.ca)

[www.ualberta.ca/science/about-us/contact-us/faculty-directory/martin-sharp](http://www.ualberta.ca/science/about-us/contact-us/faculty-directory/martin-sharp)



# The priorities for domestic and international Arctic research in the United States

The priorities for domestic and international Arctic research in the U.S., including the work of the United States Arctic Research Commission (USARC), are detailed here

The United States Arctic Research Commission (USARC) is an independent agency that provides advice to the President and Congress on both domestic and international Arctic research by reports and recommendations.<sup>1</sup>

Congress created USARC through the Arctic Research and Policy Act of 1984. In January 1985, President Reagan established the agency through [Executive Order 12501](#). The remit of the USARC can be summarised as follows:

- To establish the national policy, priorities and goals needed to put together a federal program plan for basic and applied scientific research in the Arctic, including physical, biological and health sciences natural resources and materials, as well as social and behavioural sciences.
- To promote Arctic research, recommend research policy and to communicate policy recommendations to the President and Congress.
- To work with the National Science and Technology Council and the National Science Foundation as the lead agency tasked with implementing the Arctic research policy and to support collaboration throughout the Federal Government.
- To provide guidance to the Interagency Arctic Research Policy Committee (IARPC) to develop and implement national Arctic research projects and a five-year plan;
- To interact with Arctic residents, international Arctic research programmes and organisations and local institutions, including regional governments to obtain the broadest possible view of research needs.

USARC's has seven Commissioners, appointed by the President and include four members from academic or research institutions; two from private industry and also the indigenous Arctic residents. Serving as an ex-officio eighth member is the Director of the National Science Foundation (NSF). In addition, advisors are appointed when required to give advice and information on specific research needs and issues of concern to the USARC plus they review draft documents and convey important information on a number of scientific and engineering disciplines.

In terms of USARC's activities, we know that they hold business meetings and conduct public hearings in Alaska and elsewhere to gain input, plus they undertake site visits and field trips to research facilities and projects throughout the Arctic region. Added to this, recommendations of USARC on Arctic research policy, for example, are published in their biennial Report on Goals and Objectives for Arctic Research, plus the Commission's Special Report series.<sup>2</sup>

## Arctic Scientific Cooperation Agreement

It's also worth noting here that U.S. Secretary of State and foreign ministers of the seven other Arctic governments signed the [Agreement on Enhancing International Arctic Scientific Cooperation](#) during May 2017 in Fairbanks, Alaska. This paves the way for access by scientists of the eight Arctic governments in Arctic areas that have been identified by the governments, including access to research infrastructure, facilities and data plus the entry and exit of people, equipment and materials. The agreement entered into force during May 2018 and, "calls for the parties to promote education, career development and training opportunities and encourages activities associated with traditional and local knowledge."<sup>3</sup>



## Report recommends Arctic research priorities

In recent noteworthy news, we discover that Fran Ulmer, Chair of the USARC, issued the “Report on the Goals and Objectives for Arctic Research 2019-2020 for the U.S. Arctic Research Program Plan”. The report affirms the need for continued scientific research and it gives, for each of the five goals, specific recommendations concerning the motivation for research and examples of current research occurring.

The Report’s goals underline these priority areas of research:

- Advance Arctic infrastructure;
- Assess arctic natural resources;
- Observe, understand and forecast Arctic environmental change;
- Improve community health and well-being;
- Enhance international scientific cooperation in the Arctic.

“The rapid rate of change in this region has galvanised attention and support for increased investment in understanding and preparing for the New Arctic,” says Ulmer. “Research and innovative technology development can help people adapt to new conditions and challenges. This report illustrates some of the opportu-

nities to engage communities, businesses, researchers and governments in this effort,” she adds.

This report guides the development of the comprehensive 5-year programme plan for the overall Federal endeavour in Arctic research. Indeed, this plan is submitted to the President for transmittal to the Congress and is revised biennially and has been prepared by the Interagency Arctic Research Policy Committee (IARPC). The most recent version of the White House IARPC plan is “[Arctic Research Plan FY17- FY21](#).”

In closing, we can see that this report is an excellent example of the USARC’s unchanging mission “to develop and recommend U.S. Arctic research policy and to build cooperative links in Arctic research within the federal government, with Arctic residents, the State of Alaska, researchers and international partners.”<sup>4</sup> ■

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# What is Polar Research and Expedition Consultancy?

Here, Wilson Cheung Wai Yin from the Polar Research & Expedition Consultancy (PRECON) tells us why this organisation was set up – to encourage the cost-effectiveness of scientific field research in the Polar Regions

**P**olar Research & Expedition Consultancy (PRECON) was founded to improve the cost-effectiveness of scientific field research and exploration projects by engaging the public about the operation and sharing the experience and professionalism with these regions. With such an approach, we help the research team achieve their goal with less of a financial burden helping to encourage more research and exploration in the Polar Regions when it comes to natural science, humanities and social science. Meanwhile, we offer the populace a unique experience as well as access to these remote

regions and the opportunity to learn about the connection between Polar Regions and humankind, to understand the scientific value of the area and ultimately, contribute to the sustainable environment.

## **Commercial research and expedition support in the Polar Region**

The history of polar exploration is concise. However, “change” has been termed a normal state of affairs in the Polar Regions, but the pace and extent of current ecological, societal and geopolitical transformations are unprecedented. These hot topics

make it essential to study the Polar Regions. To enhance the awareness of the Polar Region and promote its importance for humankind in terms of wilderness value, an international cooperation space and a spirit of exploration are urgently needed.

Having served in the Polar expedition industry since 2011, we noticed that most Polar research and expedition projects were supported at the national level, which limited the researchers, as well as non-government-funded institutes access to these regions and freedom of exploration, even they have vast ideas and projects. Due to





the extreme conditions and remoteness of the Polar Regions, the operational cost of each expedition is a primary concern for most scientists to conduct field research, not to mention the general public who interest in polar research.

To fill the niche market, we offer a professional and complete management package that facilitates the commercial/civil led expedition at a wide range of destinations, especially in extreme and remote regions, namely the Arctic (all seven countries), the Antarctica, Greenland, Nepal and Tropical Regions in Southeast Asia. Our services cover both planning and operating aspects, including itinerary design and expedition planning, permits application and environmental impact assessment, Polar safety training & pre-expedition training expedition project management and logistic consultation, as well as safety and risk management, equipment pilot test and technical support. Our one-stop tailor-made advice and solutions can contribute significantly when it comes to

supporting scientific research and expedition projects.

## **Why should the shareholder choose Precon?**

We believe the key to a successful expedition is based on all the elements of preparation! Therefore, PRECON has put the most effort into offering expedition planning advice, providing logistical solutions and risk assessment helping the shareholder make a reliable decision in polar-related business. An expedition inevitably incurs various risks but a carefully planned expedition can minimise risk and cost while maximising the outcome. In other words, a consultant with a broad network of specialist, hard-won knowledge and experience is crucial to the success of polar exploration and research.

We are specialists in risk management and we put safety first. Working in the polar field, no matter how well we prepare and plan, we cant predict every outcome. The local weather, ice condition, regulation and biosecurity

would influence the whole action and management. Therefore, working in the polar regions, we always need an adaptable mindset to plan for the rapidly changing conditions. Besides the polar safety training we offer, with our broad network and considerable polar experience, we can identify the potential threats and hazards in advance and generate efficient preventive measures to mitigate the risks. In the event of any problems arising, we can react effectively and tackle the problem with our experienced pre-planned solutions.

A permit application is the starting point for legal research on the Polar Regions. Handling various laws and regulations can be confusing and time consuming for new scientists. We assist our clients in preparing the materials needed for a permit application to ensure the expedition is adequately documented. Our experiences and expertise will help researchers deal with the complex regulations and also the environmental impact assessments.

We are experienced and professional in managing an expedition. Our experts can generate the best day-by-day itinerary to suit the needs of each expedition. Apart from the logistics, our consultation service also offers first-hand, specific and unrivaled knowledge for your team, including operational tactics, budget control, expedition trends, itineraries implementations and even pioneering technologies in the field, such as manned submarines, helicopters, ROVs. etc.

Thus, to collaborate with us for polar scientific field research and exploration expedition is undoubtedly essential to maximise the outcomes, safety, efficiency and productivity of the projects.



## Showcase 1: Geology Survey at East Greenland

We were invited to join a team of geologists in North Eastern Greenland for a two-month season of fieldwork. Our primary role here was in facilitating the safe and efficient operations in a remote region, which has unique risk factors.

The study aimed to survey particular areas of the North East Greenland coast to find source rock and reservoir rock for fossil fuels. The survey spanned a large geographic area and it was deemed necessary to fly in inflatable boats by Twin Otter and then conduct camp moves by small boat.

Typical daily operations consisted of medium distance travel by inflatable boat 20-30 miles, hiking into the survey area, scientific survey assistance, sample collection and return to camp. Because of daily sightings of polar bears, we kept a night watch rotation, with every member taking a three and a half hour shift. Particular



challenges going into the field season were lots of late-season sea ice in the fiords we were working in, operating in high-density polar bear habitat and remote deep field location.

As our responsibility lay primarily in safe operations, we maintained a bear safe camp, as well as providing boat and equipment maintenance and

field training for all members. When out doing survey work, we were often able to assist in data collection and sampling, which substantially sped up the process of scientific work.

Ultimately, the field season was deemed a success. All of the survey areas were covered on time and all risks were managed well.





## Showcase 2: Student Polar Research Programme (SPRP)

Starting in 2017, we launched the Student Polar Research Programme (SPRP). By involving donors, the young researchers, as well as the marine scientists, we offer a sustainable way to travel and explore the polar region.

During the Arctic seasons of 2018 and 2019, we assisted the Hong Kong research teams with professors, post-graduate researchers, environmental NGO leaders, environmental engineers, high school students and their teachers and donors to conduct field studies at Svalbard, Norway. PRECON provided one-stop services from itinerary design, expedition team staffing, charter vessel, permit application, document management and logistic arrangement to equipment pilot test.

As a result, the donors had a unique experience at the polar region with the scientific team and connected the wilderness in the deep root. Meanwhile, the young scientists enjoyed the lower cost of operation to reach the field for collecting data. PRECON



enacted their research in marine microalgae, ice algae, Arctic circulation, lichen, a dangerous pollutant, nuclear radiation and microplastic. PRECON assembled a team of experts to work closely with the students, identified particular sites of scientific interests, supervised data collection plans, data management, analysis and report and provided them with sound advice and reliable logistic support to maximise the outcomes, efficiency and productivity of their projects, making the expedition an inspiring and life-changing experience to the students.



**Wilson Cheung Wai Yin**  
Polar Research & Expedition Consultancy  
Tel: +852 622 507 75  
info@preconsultancy.com  
www.preconsultancy.com



# A new vision of plastic production and plastic use

Antonello Pezzini, Member of the European Economic and Social Committee  
shares his new vision of plastic production and plastic use

**M**ore than 25.8 million tonnes of plastic are currently produced in Europe every year, employing some 1.5 million people. But only 30% is recycled and the percentage of waste going to landfills or incinerators is still too high.

To stop this practice, which is polluting the land and the seas, eco-design efforts need to be stepped up and all stakeholders – private companies, public bodies and ordinary people – have to be brought into the process. Plastic must in the future be developed as part of a new smart, innovative and sustainable vision, in which design and production are capable of meeting reuse, repair and recycling requirements.

The introduction of plastic bottles has unfortunately consolidated the principle of one-way recipients. This has created significant environmental risk, since polyethylene like all oil-derived plastics is not biodegradable: on the contrary, it is virtually indestructible.

Waste recovery consequently offers an initial solution. According to World Economic Forum data, only 14% of plastic bottles are recycled. 40% end up in landfills, 14% in incinerators and/or energy recovery plants. 32% are discarded in the environment. Under these conditions, plastic that is not properly disposed of is not only a serious problem for the ecosystem but also represents a huge waste.

If the plastics deriving from oil processing are not destroyed, their production must be limited and existing plastics reused. Something we could do immediately is to extend bottle lifetimes, stopping them from being discarded in the environment after a single use. Proper differentiation of plastic waste generates economic gain and creates new jobs, but above all is beneficial for the environment and public health. In other words, the aim

should be to prohibit deposit in landfills and promote the creation of new recycling facilities through tax incentives, standardisation and the simplification of the regulatory framework.

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**“With regard to marine litter, there is an increasing need for coordination between initiatives by the European Commission and the International Convention (Marpol) in order to prevent pollution produced by ships, although there must be appropriate exemptions for small vessels and low-traffic ports.”**

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Bottle recycling is already a consolidated process in the textiles sector. For example, 54,000 1.5-litre plastic bottles can be recycled and converted into an excellent polyester that can be made into 7,000 backpacks. After successive transformations, it is no longer surprising that a plastic bottle may end up on display in the window of a luxury shop. Newlife®, a polyester polymer obtained from plastic bottles, took its place alongside silk and chiffon in 2012.

There is no reliable data on the amount of plastic that ends up in the sea. The best estimates suggest that the total weight of plastic waste in the oceans amounts to 150 million tonnes, representing a significant volume in cubic metres.

And matters are still getting worse. In 1965, for each kilo of fish there were 10 grammes of plastic in the sea (a ratio of 100:1); in 2014, 200 grammes (a ratio of 5:1) and, according to forecasts, in 2050 for each kilo of fish, there will be 1 kilo of plastic in the sea. Plastic bottles that end up in the sea take almost a thousand years to dissolve. In the meantime, they float and are carried by currents. They slowly break down into increasingly small pieces. Ocean currents push plastic waste towards a number of specific marine areas. There are



Antonello Pezzini

The fisheries fund (EMFF) should be tapped to involve fishing organisations in organised marine waste collection. When properly trained, fishermen could supplement their fishing earnings by turning to the collection and recycling industry. The proposal for a directive on port reception facilities for plastic introduces new standards to combat the problem of marine waste, with measures intended to guarantee that waste produced on board a ship or collected at sea is not dumped but brought back on the land to be processed properly. Provision is also made for measures to reduce the administrative burden on ports, vessels and the competent authorities, together with incentives for fishermen engaged in waste collection.

The same approach applies to cleaning up rivers using cooperatives. It is estimated that between 1.15 to 2.41 million tonnes of plastic waste currently enter the seas every year from rivers. The top 20 polluting rivers, mostly located in Asia, account for 67% of the global total of plastic waste flowing into the oceans.

Today, however, the main eco-sustainability challenge is to come up with non-polluting and fully biodegradable plastics. The future seems to belong to bioplastic: scientific research has made great strides in this sector. The supply of oil-derived plastic bags has been banned since 1st January 2009: instead of plastic, the use of Mater-Bi® is being promoted, a carbon and hydrogen polymer obtained from maize starch. ■

at least four islands of plastic, the largest being in the North Pacific; others have been identified in the South Pacific, the Atlantic and the Indian Ocean.

Microplastic consists of plastic debris smaller than 5 mm. Microplastic derives either from cosmetic products ("microbeads") or detergents; they can also be the result of larger plastic objectives breaking up. The small size of this debris means it is difficult to collect and it represents an invisible threat to the food resources of marine animals.

With regard to marine litter, there is an increasing need for coordination between initiatives by the European Commission and the International Convention (Marpol) in order to prevent pollution produced by ships, although there must be appropriate exemptions for small vessels and low-traffic ports.

### Antonello Pezzini

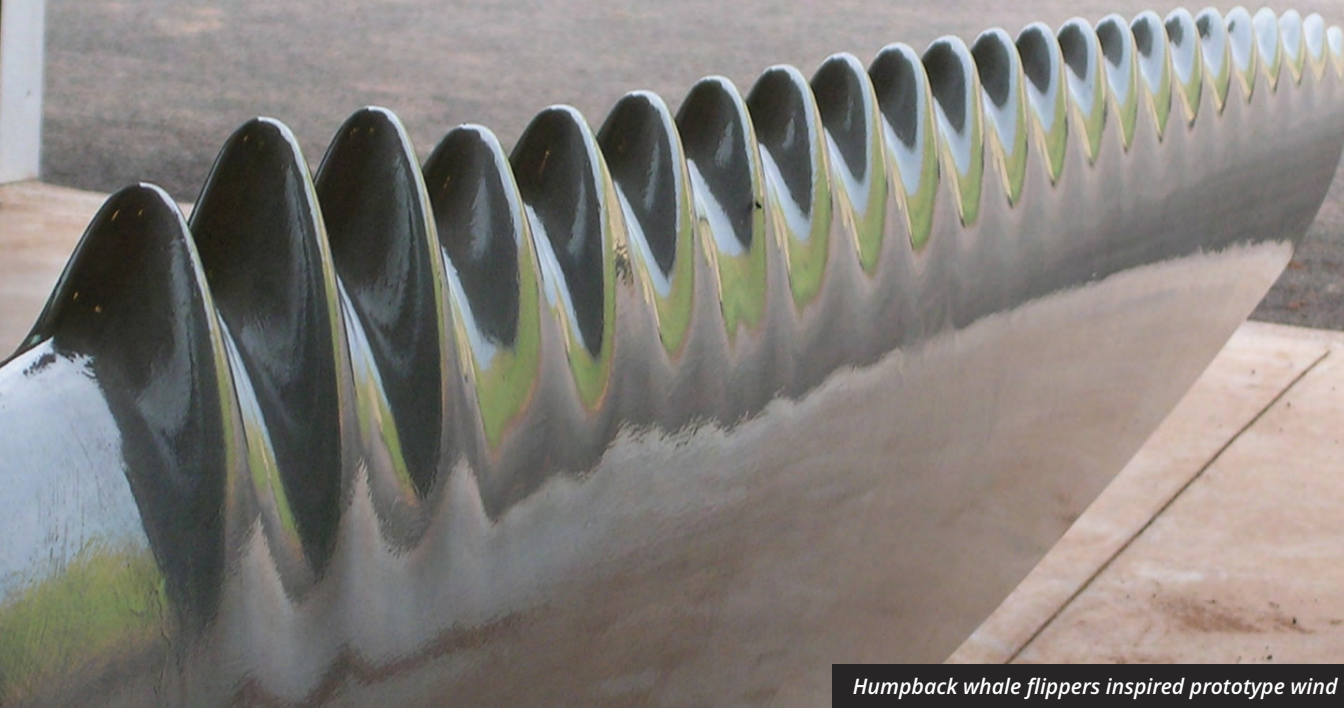
#### Member

European Economic and Social Committee

Tel: +32 (0)2 546 90 11

[www.eesc.europa.eu](http://www.eesc.europa.eu)

[www.twitter.com/EU\\_EESC](https://twitter.com/EU_EESC)



*Humpback whale flippers inspired prototype wind turbine blades*

# Building a sustainable future from our oceans

To address modern-day sustainability challenges, the EMBRC-ERIC was established to bridge the gap between marine biological research and innovation

**M**arine systems are essential to life on Earth. Oceans control our planet's climate and provide a rich and largely unexplored reservoir of biodiversity. Yet, as a result of the continued growth of human populations and the associated increasing demand for energy and resources, there is a pressing need to develop sustainable solutions to maintain functioning of marine ecosystems and the planet as a whole.

By bringing together a consortium of European marine research facilities across several countries, the [European](#)

[Marine Biological Resource Centre \(EMBRC-ERIC\)](#) enables access to marine biodiversity on a continental scale, as well as the associated research tools, facilities and expertise.

As such, the research infrastructure delivers a mechanism for the provision of large scale and high-quality marine science, thereby providing a platform for innovation which, in turn, could have a direct impact on our planet's sustainability.

The potential for innovation is particularly high in the marine realm due to

the biodiversity that is yet to be discovered and the wide range of recent novel technologies and concepts that stem from marine ecosystems. One particularly topical example is that of plastics, a product which is derived from non-renewable materials, takes hundreds of years to decompose, is detrimental to animal life and is making its way into the food chain.

Given our dependence on plastic for everything from food packaging to automotive components, innovators are seeking alternative materials and, thanks to the marine environment,



Image: © Humberto Ramirez/Getty



*Squids are the source of a protein that could be used to make garments last longer*

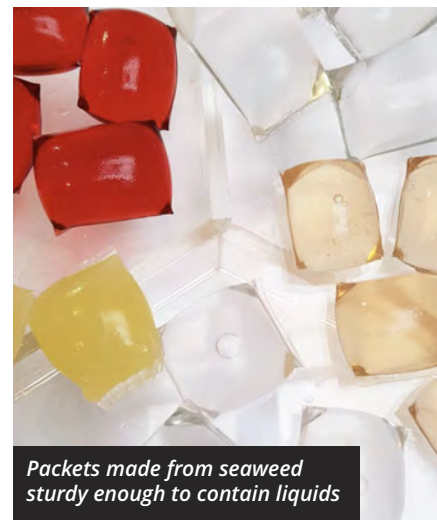
biodegradable, seaweed-based straws, packaging and water pouches are now making their way onto the market.

Innovative, marine-based products are also advancing scientific research in other fields of science. In cellular science, collagen used in cell culturing procedures historically came from terrestrial mammals such as pigs and cows, which brought with it a risk of disease as well as a number of environmental issues. Today, jellyfish collagen is being commercialised. Not only is this marine collagen source abundant due to proliferating jellyfish populations, it is also safer. Another marine-inspired innovative material is Squid Ring Teeth (SRT) protein. Researchers recently discovered that this protein can be used to coat textiles to prevent garments from wearing, thereby increasing the longevity of clothing and thus reducing the consumption of clothes that shed microfibers that entering the oceans. Originally isolated from squid suckers, SRT is now produced in the laboratory using genetically modified bacteria, eliminating the need to maintain these relatively fragile, migratory marine animals.

Marine models have also led to design innovations through biomimicry, the development of structures based on forms observed in nature. For example, the shape and angle of humpback whale flippers have inspired prototype wind turbine blades which are not only more efficient, but also spin at lower wind speeds. The swaying movements of kelp have inspired novel subsurface structures which move with passing waves and currents and thereby generate electrical energy.

These few examples demonstrate how the marine realm can inspire innovation across diverse fields, from cellular science to the fashion industry, and also affirms the marine environment as a leading innovative influence and a source of innovative products. The resulting products have the potential to reduce our impact on our planet through the use of biodegradable and less-polluting products, lessen our reliance on non-renewal resources, increasing the efficiency of existing systems, and thereby improve world-wide sustainability.

Further innovation will be facilitated by research infrastructures such as



*Packets made from seaweed sturdy enough to contain liquids*

Image: © Ooho

EMBRC-ERIC, as access to organisms, equipment and expertise are an essential part of developing new products. Furthermore, the increasing number of innovations originating from marine ecosystems reflects how much is yet to be discovered.



**Sidonie Gras**  
**Scientific Officer and Project Manager**  
 Tel: +33 144 277 266  
[sidonie.gras@embrc.eu](mailto:sidonie.gras@embrc.eu)

**Nicolas Pade**  
**Executive Director**  
 Tel: +33 144 278 115  
[nicolas.pade@embrc.eu](mailto:nicolas.pade@embrc.eu)  
 EMBRC-ERIC (European Marine Biological Resource Centre)  
[www.embrc.eu](http://www.embrc.eu)  
[www.twitter.com/EMBRC\\_EU](https://twitter.com/EMBRC_EU)

# Can innovation and new technology tackle environmental issues in the marine environment?

Tessa Harding, Director, Aquatic Ecology, at Thomson Environmental Consultants asks if innovation and new technology can tackle environmental issues in today's marine environment

The recent BBC documentary 'Climate change: The Facts' presented by David Attenborough highlighted the significant issues facing the marine environment linked to climate change. Seawater temperatures are projected to rise by an average of between 1 and 4°C by 2100, with increases in sea level rise that will threaten many coastal cities. A less well publicised, but equally pressing issue is the acidification of the oceans due to absorption of carbon dioxide. Currently, the ocean absorbs more than 26% of the carbon dioxide emitted to the atmosphere from human activities. <sup>(1)</sup> Increased acidity caused by carbon dioxide lowers the availability of calcium carbonate, a naturally occurring mineral in seawater, needed by marine organisms including plankton. A collapse in populations of these organisms will not only result in the loss of marine biodiversity but it will also have a significant effect on fishing and aquaculture. The Extinction Rebellion campaign calls for the UK to adopt a zero-carbon target by 2025. Climate scientists suggest that 2050 is more realistic, but how do we achieve even this target? This article reviews some of the challenges to the marine environment from climate change and other pressures, whilst exploring new technologies and innovations that are aiming to address them.

In the UK, the marine environment represents a key source of renewable energy with offshore wind now serving 9% of our energy needs and set to increase. Ambitious government investment 15 to 20 years ago allowed the wind industry to mature, reducing the cost of technology and turbine installation. Other marine renewable technologies, including tidal and wave power, have struggled to attract and sustain the same long-term vision. Government support for the Swansea Bay tidal lagoon scheme was withdrawn in 2018 on



*Microplastic granules on a shrimp (scale 0.5 mm)*

cost grounds, given the cost per unit of energy levied by the developer to the government to cover the cost of construction (known as the strike price), was £89.9 per MWh over 90 years, compared with £57.50/MWh for 15 years for offshore wind. <sup>(2)</sup> However, the first offshore wind farms required strike prices of £150/MWh, demonstrating the cost reduction benefits from a mature industry with growing private investment. Our coastline has some of the largest tidal ranges in the world, which is estimated to represent around 50% of Europe's tidal resource. <sup>(3)</sup> The UK has the opportunity to be a market leader in this field.

The issue of plastics in the marine environment conjures up images of the floating islands of waste. However, it is the small particles, known as microplastics, made up of tiny plastic beads, granules, fibres and fragments less than 5 mm in diameter that represent the greatest threat to marine wildlife. As well as replacing food in the stomachs of marine animals, plastics can

release chemicals as they degrade with potentially toxic effects. There is currently a wide range of research focused on the effects of microplastics. For example, Exeter University is collaborating with a U.S. environmental charity, The Rozalia Project to investigate these toxic effects. <sup>(4)</sup> Here at Thomson Environmental Consultants, our Principal taxonomist Ruth Barnich has established a formal classification and recording system for microplastics for use in the laboratory analysis of marine invertebrates. The system has been shared with UK Government agencies with the aim of improving consistency in the analysis of impacts on marine wildlife from microplastics.

The Great Pacific Garbage Patch is a term coined to describe an accumulation of plastic waste caught in circular currents or gyres in the Pacific Ocean. <sup>(5)</sup> Attempts have been made to clean up the patch, using a bespoke system comprising a 600m long boom or floater, with a 3 metre deep skirt for collecting floating plastic debris. The cleaning array moves faster than the plastic waste, thereby trapping it within the skirt for subsequent recovery. <sup>(6)</sup> The system has faced some teething problems and is now undergoing a further development phase before being launched for a second attempt. <sup>(7)</sup>

Commercial over-exploitation of fish stocks is another issue affecting global marine ecosystems. UNESCO report that 13% of global fisheries are believed to have collapsed due to over-exploitation. Even with a managed quota system such as the EU Common Fisheries Policy, there is a tendency for overexploitation – capitalising on apparent stock increases and responding slowly to decline. <sup>(8)</sup> The capacity of fishing fleets and their ability to exploit a wider range of species and larger areas has increased considerably and at a global scale. The designation of Marine Protected Areas (MPA's), in which fishing activity is prevented or heavily reduced, coupled with quota systems, are generally acknowledged to be the most effective methods for reducing or even reversing fishing pressure. <sup>(9)</sup>

On a more local scale, an innovative method developed by the Nature Conservancy in Australia uses facial recognition software to create an app which allows fishers to collect information on catches at sea. By collecting, organising and sharing data using the app,

known as FishFace, the aim is to help fishers manage fish stocks and reduce by-catch. The app won Google's 2016 Impact Challenge. Additionally, simple innovations, like modifications to the shape of fishing hooks are being used in the Pacific island nation of Palau to target species and reduce bycatch. <sup>(10)</sup>

Pressures on the marine environment will increase with growth in the human population. Our seas also offer opportunities for renewable energy generation and sustainable food production. New and innovative technologies underpinned by objective scientific research must form part of the solution to achieving these goals. However, significant long-term investment, led by strong, political vision, is also needed to take innovations from simply a good idea to on-the-ground delivery at a local and global scale. ■

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**Tessa Harding**

**Director, Aquatic Ecology**

Thomson Environmental Consultants

Tel: +44 (0)1483 466 000

[enquiries@thomsonec.com](mailto:enquiries@thomsonec.com)

[www.thomsonec.com](http://www.thomsonec.com)

[www.twitter.com/thomsonec](https://www.twitter.com/thomsonec)





# Developing convenient consumer products from pelagic fish in Europe

Turid Rustad, Professor at NTNU explains the development of convenient consumer products from pelagic fish, including the recent growth of European fish consumption

The lifestyle and dietary patterns of people are changing. In the western world, the more time-stressed lifestyle has led to an increased intake of processed and fast food. A significant global increase in fish consumption has enhanced people's diets all over the world making them more nutritious. In 2017, fish accounted for about 19% of the global population's intake of all animal protein consumed (FAO, 2018). Europeans are regular consumers of fish and seafood products. European fish consumption has been continuously growing during the last few decades and currently, 42% of European consumers eat fish and seafood products at least once a week.

However, the consumption of pelagic fish species is much lower compared to the consumption of other fish species, such as salmon or cod, although the total catch of these fish species has been gradually increasing during the last several years in European Union and Norway.

One of the aims of the Prohealth (JPI: Preserving positive health effects of pelagic fish) project was to develop model products with pelagic fish. Using pelagic fish and meeting the consumer expectation for healthy food, will increase the use of pelagic fish for human consumption and local processing which is important from a global nutritional and environmental

perspective. To develop the right type of model products, a survey on consumer preferences for fish product purchasing decisions was carried out by NMFRI (National Marine Fisheries Research Institute) in Poland. The study was carried out in the four countries participating in the project. The consumers in all four countries understand that diet is important for health and is one of the main factors determining a healthy life.

Consumers also believe that we should eat less processed food and there is a negative perception of industrial food. Eating fish – especially fatty fish is widely recognised as being a significant factor affecting health,

with 42% of the respondents saying that there is a need to increase their intake of fish, especially fatty fish. As to what type of fish products are preferred, there is a variation between countries – not frozen convenience products, such as fish burgers, fish cakes and fish dishes ready to heat in the microwave. Oriental products like sushi are much more popular in Norway and in Italy than in Ireland and Poland. On the other hand, canned fish is regularly bought in Ireland and Poland while it is less popular in Norway.

The reasons for buying fish are both that the consumers like the taste of fish (64%) and the pro-health effect of eating fish (61% of respondents). More than 50% of the respondents also say that they eat fish because it is a regular component of their diet and/or that they need to buy fish for their children.

The main parameters for selecting fish products was the species used, the price, the brand, the country of origin and the size of the package. This shows that to develop new fish products health or nutritional value is not the only parameter checked. Among the pelagic species, mackerel had a good reputation among the respondents while herring was less popular. There are also generational differences, the older consumer segment buys more fresh fish and is less convinced of the need for convenience products while the younger generation is much more interested in convenient products. The consumer study also shows that young consumers now have little interest in pelagic fish. The reason for this needs to be further studied but could it be because of the taste? There are

many convenient products currently available, such as canned sprat and mackerel, brined herring and herring salads). What type of products should be developed to increase the consumption of pelagics among consumers?

One of the reasons for the low consumption of pelagic fish can be the lack of diversity when it comes to processed pelagic fish products. Traditionally, small pelagic commodity groups have been used in the manufacture of canned fish products, such as mackerel in oil or tomato sauce, salted herring, canned sardines, etc. To increase the consumption of pelagic fish, there is a need to increase the diversification of the fish products available. One of the solutions is to develop new consumer-friendly ready-to-eat products using pelagic fish in conventional fish product formulations and study consumer acceptance of the developed products. This could include Sous Vide products, fish cakes, fish ball, fish burgers, etc. with higher omega-3 fatty acids and vitamin content.

Fish cakes have traditionally been consumed in many European countries, including Norway and Poland. In Scandinavian countries, they are generally made by pan frying or frying in the oven from whitefish species, such as cod or haddock. At the same time, fish cakes made from fatty fish, such as salmon and shellfish have recently become popular in Norway and Asian countries. Fish cakes from pelagic fish have been a traditional product in Norway but pelagic fish is not commonly used for the production of fish cakes today. In the ProHealth project, fish cakes with up to 50% mackerel were tested. The results show that fish cakes with mackerel were well

accepted by the consumers compared to fish cakes made from haddock. Sensory studies indicated that the increase in mackerel content positively affected the juiciness and aroma of fish cakes, however, the darker colour was perceived as negative.

Another possibility for ready to cook products is to develop Sous Vide products. Sous Vide combines low cooking temperatures with vacuum packaging and may delay the spoilage of fish through inactivation of endogenous proteases and lipases, at the same time preserving the sensory and nutritional quality of the product. Experiments have shown that Sous Vide treatment of both mackerel and herring is promising regarding microbial shelf life but that there is a need to add antioxidants to preserve the healthy fatty acids during storage.

In developing new products, both the nutritional value and the health beneficial components as well as the sensory quality (flavour, texture), are preserved throughout the whole processing chain.



**Turid Rustad**

**Professor**

Norwegian University of Science and Technology

Tel: +47 7359 4066

[turid.rustad@ntnu.no](mailto:turid.rustad@ntnu.no)

<https://www.ntnu.edu/>

# Conserving coastal and marine ecosystems and resources

The National Oceanic and Atmospheric Administration (NOAA) have a mission to understand and predict changes in weather, climate, oceans and coasts, as this article reveals, with a special focus on their work to conserve and manage coastal and marine ecosystems and resources

The National Oceanic and Atmospheric Administration (NOAA) are a U.S. agency that aims to enrich life through science. Their scope of work goes from the surface of the sun to the depths of the ocean floor, as they do what they do to ensure that the public is kept up to speed with the changing environment that surrounds them.

By way of background information, we know that President Thomas Jefferson founded the U.S. Coast and Geodetic Survey (as the Survey of the Coast) to provide nautical charts for the maritime community to ensure safe passage into American ports and along their extensive coastline, way back in 1807. <sup>(1)</sup>

Today, NOAA's vital work includes severe storm warnings, daily weather forecasts and climate monitoring, as well as coastal restoration, fisheries management support for marine commerce.

Dedicated scientists at NOAA use high-tech instrumentation and cutting-edge research to give citizens, emergency managers, planners and other decision makers with reliable information they need when it is required. <sup>(2)</sup> Certainly, science underpins all NOAA does, for example, when it comes to weather forecasts and warnings, climate information, coastal management recommendations, fishing regulations and satellites in space. Many of NOAA's scientists are respected as national and international experts in their fields and the quality of their work is considered to be exemplary. <sup>(3)</sup>

The mission of NOAA can be summed up as follows:

1. To predict and understand changes in weather, climate, oceans and coasts;

2. To share such knowledge and information with other people;

3. To manage and conserve coastal and marine ecosystems and resources. <sup>(4)</sup>

## Coastal and marine ecosystems and resources

This article will focus on the third aspect of NOAA's work mentioned above that concerns managing and conserving coastal and marine ecosystems and resources. We know that NOAA has direct authority to sustain and to regulate marine fisheries and their ecosystems, protect and restore habitats and ecosystems, protect endangered marine and anadromous species, conserve marine sanctuaries and other protected places, respond to environmental emergencies and aid in disaster recovery.

In April this year, a new web-based interactive tool for ocean mapping and planning was created to give everyone from ocean industries to coastal managers, students, plus the public the chance to be an ocean explorer from their own computer. The tool was made by the NOAA and the Department of the Interior's Bureau of Ocean Energy Management.

The new [OceanReports web tool](#), gives users specialised 'ocean neighbourhood analyses' including graphics and maps by analysing no less than 100 ocean datasets at the same time.

Did you know that U.S. ocean waters make up a total of almost four million square miles and is one of the largest Exclusive Economic Zones (EEZ) globally? Did you know that detailed information about habitats and



## The Sargasso Sea

Did you know that the Sargasso Sea can be found entirely within the Atlantic Ocean and it is the only sea that does not have a land boundary? The Sargasso Sea is well-known for a genus of free-floating seaweed called *Sargassum*. It's true to say that there are a number of different types of algae located in the world's oceans but the Sea is unique because it harbours *holopelagi*, a species of *Sargassum*. By way of further explanation, *holopelagi* means that the algae reproduces vegetatively on the high seas, as well as freely floating around the ocean. Added to this, we know that other seaweeds reproduce and begin life on the floor of the ocean.

*Sargassum* hosts an amazing variety of marine species, for example, it is an essential habitat for crab, fish, shrimp and other marine species that have adapted to this environment. In addition, did you know that turtles use *Sargassum* mats as nurseries where hatchlings have food and shelter?

Threatened and endangered eels, as well as porbeagle shark and dolphinfish, as well as white marlin, have made the Sargasso Sea their place of habitation. Humpback and commercial fish, such as tuna and birds migrate through the Sargasso Sea and depend on it for their sustenance.

The Sargasso Sea is defined only by ocean currents which contrasts sharply with the other seas in the world which are to some extent, of course, characterised by land boundaries. The Gulf Stream establishes the Sargasso Sea's western boundary, while the Sea is further defined to the north by the North Atlantic Current, to the south by the North Atlantic Equatorial Current and to the east, by the Canary Current. <sup>(5)</sup>

species, industries in the area, potential hazards such as undersea cables or shipwrecks, the economic value of ocean commerce and other detailed oceanographic information can be at your fingertips using the OceanReports tool?

"The world's largest collection of 'ocean intelligence' can now be accessed to help sustain and grow one of the world's largest blue economies," says Neil Jacobs, Ph.D., Acting NOAA Administrator. "Whether it's aquaculture siting, marine transportation, or offshore energy, OceanReports puts this data at our fingertips and gives us an edge as we continue to grow our national economy."

In addition, while OceanReports offer an abundance of data for use by science and industry, it's easy to use in the classroom to help students studying biology, chemistry, geography and even other disciplines like economics, according to the NOAA. This excellent work is certainly a fitting example of how the NOAA as a U.S. agency aims to enrich life through science, as this article draws to a close.

"With such a diverse range of ocean uses and stakeholders, the OceanReports tool greatly increases one's

ability to understand and manage the resources in the complex ocean environment," comments BOEM Acting Director, Walter Cruickshank. "Our team worked diligently with NOAA to create this tool, which benefits the ocean community in addition to helping BOEM carry out its mission—the responsible development of ocean energy and marine mineral resources for the nation." <sup>(6)</sup> ■

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# The Sargasso Sea Commission: High seas conservation

Dr David Freestone and Professor Howard Roe explore how the Sargasso Sea Commission could be a new paradigm for high seas conservation

A place of legend, but also a fundamental part of the ocean, the Sargasso Sea encompasses two million square miles in the subtropical North Atlantic Ocean, enclosed by rotating currents. The only sea without land boundaries, its importance derives from its interdependent mix of its role in global scale ocean and earth system processes, its socioeconomic values and its role in scientific research.

Two species of *Sargassum* give the Sea its name. Trapped within the rotating current system and dubbed the golden floating rain forest of the Atlantic Ocean, *Sargassum* rafts host specialised communities of animals and provide nursery and feeding areas for many endangered and endemic species. *Sargassum* provides rare open ocean shelter for spawning fish including billfish, tuna, and marlin and young turtles spend their “lost years” sheltered in the mats.

The Sargasso Sea also acts as a cross-roads in the North Atlantic for a number of iconic migratory species. Humpback whales migrate annually between the Caribbean and sub-Arctic, and Porbeagle sharks use the area to give birth, but the most mysterious ocean migrants are the endangered European and American eels. Both species live for many years in freshwater before migrating thousands of kilometres to the Sargasso Sea to spawn and die. Their larvae



return to the rivers, develop into adults, and migrate back across the Atlantic.

Many aspects of this extraordinary life cycle remain unknown, but recent research identifies their spawning areas within the southern Sargasso Sea. Declining populations of both species in recent years with resulting losses to multi-million-pound coastal fisheries -the Sargasso Sea is vital for the survival of both the eels and the commercial fisheries outside the area.

It is not only eels that are commercially valuable. The Sargasso Sea contributes significantly to global and local economies. The economic value of the Sargasso Sea, which some estimate as millions of pounds, contributes to global and local economies by connections to various fisheries,

whale watching, turtle tourism, and the benefits of coral reefs surrounding Bermuda, as well as indirect benefits such as climate regulation, nutrient cycling and habitat services.

The Sargasso Sea is hugely important for our understanding of the role of the oceans in climate change. The Bermuda Institute of Ocean Sciences hosts the longest running time series of open ocean measurements which show rising temperatures and increasing acidification of the ocean since 1954. These data provide indisputable evidence of global warming and ocean acidification, and continue to deepen our understanding of the ways the global ocean works and responds to change.

Climate change alters ocean structure and ecology, which threatens the

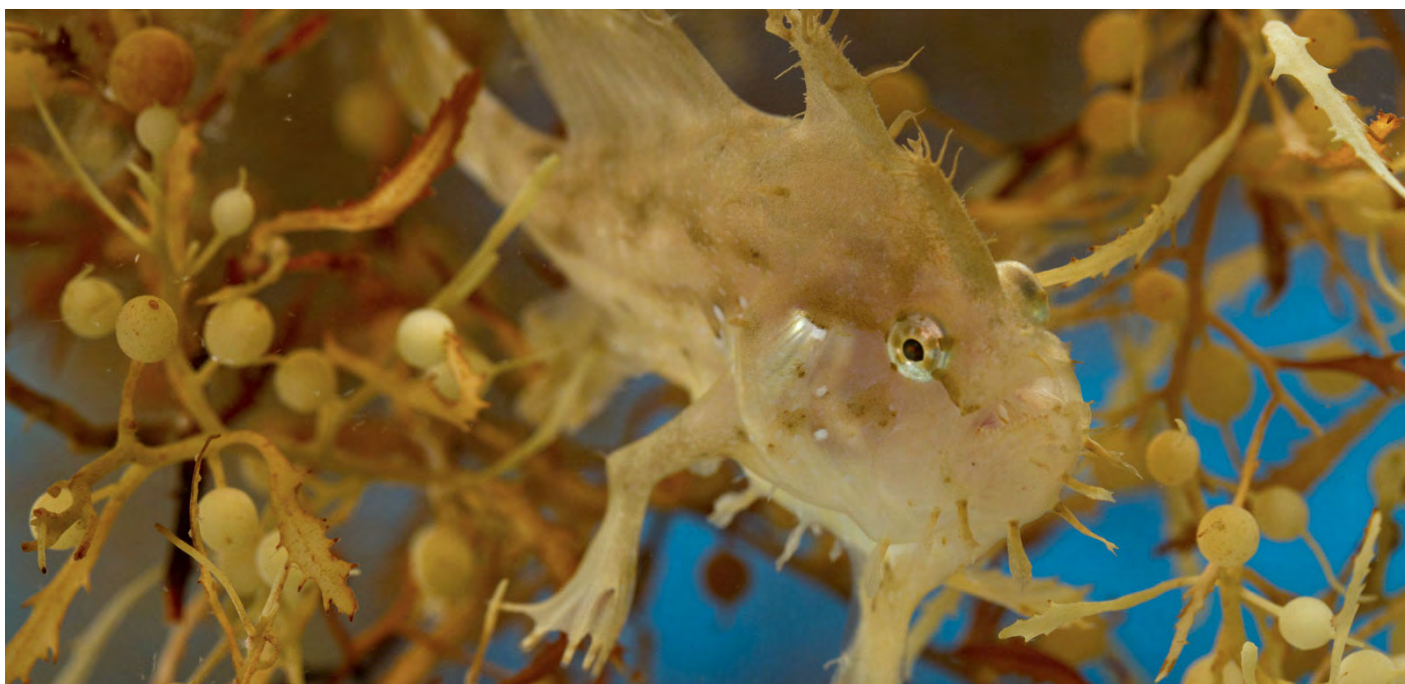


Image: © JP Rouja

Sargasso Sea. Plastic waste may end up in ocean gyres, the rotating current systems which include the Sargasso Sea. There is evidence of increased fishing and shipping activity. Sargassum itself may also pose a threat! Since 2011, beaches in the Caribbean, West Africa and South America have been inundated with thousands of tons of Sargassum originating south of the Sargasso Sea.

The culprit is a previously rare form of Sargassum which has suddenly become abundant and may have ecological impacts as it is less attractive to commensal communities and feeding fish. The cause of its increased prevalence is unclear but likely involves nutrient run-off from rivers, dust from the Sahara, increased ocean warming and possible current changes. Currents carry the weed onto beaches, causing huge social and economic problems to local communities and to local ecology.

But the biggest challenge facing the Sargasso Sea is a legal one. The

Sargasso Sea falls within the high seas-the 50% of the planet outside national jurisdiction. To address this challenge, five governments convened in 2014 to sign the Hamilton Declaration on Collaboration for the Conservation of the Sargasso Sea and to establish the Sargasso Sea Commission to act as a steward for this extraordinary area. Five more governments have since joined and others may follow.

The Sargasso Sea Commission is a new paradigm for the conservation of areas beyond national jurisdiction, convening stakeholders from multiple countries and organisations to address issues that fall outside national agendas. Parties to the Convention on Biological Diversity have agreed that the Sargasso Sea be included on a list of Ecologically or Biologically Significant Areas. Using this as a basis, in 2015 the Northwest Atlantic Fisheries Organisation declared a moratorium on bottom trawling on Sargasso Sea seamounts in its Area and gear restrictions on midwater trawling.

The Commission is working to protect the Sargasso Sea alongside a number of governments and partners, to protect the migratory range of the European Eel, to regulate vessel activities and to conserve threatened fishery resources. It is also working with NASA which is developing comprehensive satellite imagery of the area. Currently funded largely through support from government supporters and private donors, the Commission seeks additional funding to continue its important work.



**SARGASSO SEA**  
COMMISSION

**Dr David Freestone**  
**Professor Howard Roe**  
The Sargasso Sea Commission



# As deep-sea science is out-paced by exploitation, can catastrophe be averted?

Dr Sandra Brooke, Florida State University Coastal and Marine Lab, explores whether the over-exploitation of deep oceans can be averted as deep-sea science continues to be outpaced

**H**umans have been exploiting the oceans for thousands of years, but focused scientific enquiry into the deep sea did not begin until the early 19th century. In 1843, Edward Forbes proposed his Azoic Hypothesis, which posited that life could not exist below 300 fathoms (550 m).

The Challenger expedition (1872-1876) was the first global survey of the deep-sea, and their dredging operations revealed great abundance and diversity of life far below 300 fathoms. The Azoic Hypothesis became obsolete and dredges were the tool of choice for deep-sea naturalists.

The middle 20th century heralded a leap forward in deep-sea research. The advent of acoustic systems to generate seafloor maps allowed scientists to locate topographic features and plumes from chemosynthetic ecosystems. Rugged ecosystems such as submarine canyons became accessible to science through the use of underwater vehicles.

Over the past few decades, technological advances have created sophisticated mapping, navigation, and imaging systems that have greatly increased our ability to study the deep. New technologies such as autonomous data collectors, new sensors, artificial intelligence (AI) and automated sample processing will continue to advance the pace of marine research.

Large research vessels and sophisticated technologies are extremely expensive, and their use is generally limited to wealthy nations. The deep North Atlantic Ocean is fairly well characterised due to significant investments in deep-sea research by Europe and North America.

Over the past decade, over 500 putative cold seeps were discovered off the western Atlantic margin, miles of deep coral reefs were mapped and explored, dense faunal assemblages were documented within submarine canyons, and many new species were described. By contrast, regions such as the Indian Ocean remain virtually unknown. Vast areas of the deep seafloor have yet to be mapped or explored and we can only guess at the kinds of secrets they hold.

With increasing pressure on financial resources, one could question the wisdom of massive expenditures in deep-sea research. Do we really need to understand a system that most people will never even see? One that is so vast and inaccessible that we couldn't possibly impact it? Why not use our precious funding to study our coastal areas, which are being overexploited, eroded and polluted within sight of human population centres?

The deep sea is not as safe from human activities as one would think. As coastal resources become depleted, nations are moving further offshore in

search of unexploited fish stocks, oil reserves, and materials needed to supply the global insatiable demand for technology.

Industrial bottom trawling is the most destructive deep-sea fishing practice, indiscriminately harvesting large quantities of target and non-target species, most of which are discarded. Deep-sea species are slow-growing and long-lived, which makes them highly vulnerable to overfishing.

In addition, large swaths of ancient deep coral habitats have been destroyed by bottom trawling, and recovery has been slow or non-existent. In return for this ecological damage, deep-sea fisheries contribute less than 0.5% of global fisheries landings, and most are heavily subsidised, suggesting they are also economically unsustainable.

Seabed mining for valuable metals is an emerging threat to deep-sea ecosystems such as manganese nodule fields, seamounts and hydrothermal vents. Many mining activities will occur on the high seas and are controlled by the International Seabed Authority (ISA). The ISA is responsible for 'protecting the marine environment from harmful effects', and is working with interested parties to develop mining regulations.

It remains to be seen however, how seamount crusts and active vents can be removed without causing harm.

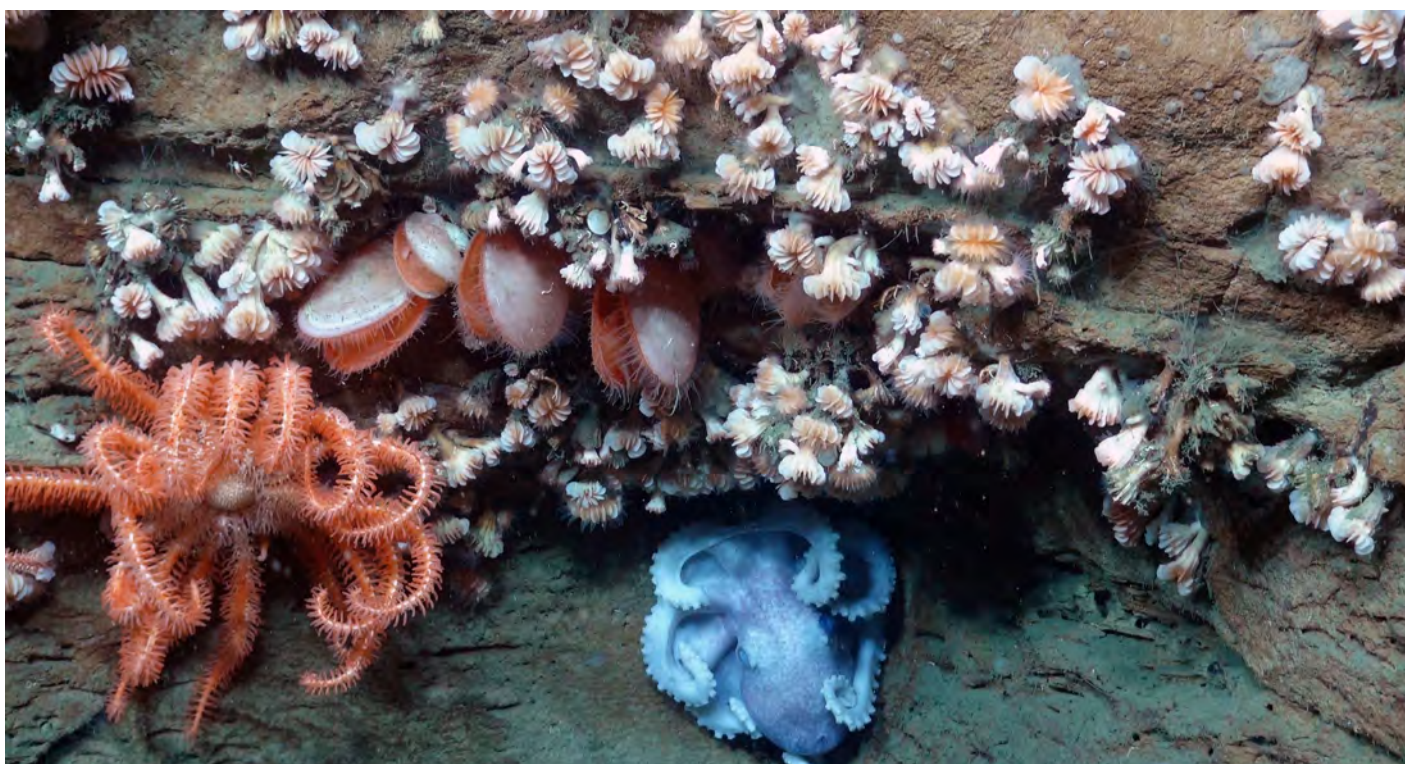


Image: © Deepwater Canyons 2013 – Pathways to the Abyss. NOAA OER/BOEM/USGS.

The face of a steep wall at the base of Norfolk Canyon (1400 m) with dense clusters of the cup coral *Desmophyllum dianthus*, a *Brissingid* seastar, a group of *Acesta* sp. fileshells and the octopus *Granelldone* sp

Superimposed on these physical impacts is the looming spectre of climate change, the effects of which we are just beginning to understand.

It is easy to place a value on the exploitation of an ecosystem, but much more challenging to calculate the value of preserving it. For example, some deep-sea ecosystems, particularly isolated hydrothermal vent systems or seamounts have high levels of endemism. Many benthic species use 'chemical weapons' for feeding or defence, and human medicines are often derived from these bio-active compounds. Microbes and metazoans that live in extreme environments can provide the key to evolution of life on earth or create new technologies. What then, is the ultimate cost of not knowing what we destroy?

Research has accomplished much over the past few decades, but cannot keep up with resource exploitation. Virgin fish stocks can be depleted

faster than scientific support for protection can be generated. Exploration contracts for mineral extraction have been granted in areas where no research exists. Terrestrial and coastal ecosystems have been mined, over-harvested and contaminated for short-term economic gain. Unless something changes, the deep oceans will suffer the same fate. As human populations increase and food security becomes a global issue, sustainable resource management will be critical.

The Magnuson-Stevens Act (MSA) is the primary law governing marine fisheries management in U.S. federal waters. One of the tenets of MSA is the 'precautionary principle', which stipulates that if an activity threatens marine resources, protective measures should be taken, even in the absence of scientific cause-and-effect evidence. This approach removes the burden on science to prove harm from industry activities and recognises the value of caution in an uncertain world.

Unless 'precautionary principles' are applied to ecosystem management globally, we risk squandering priceless and irreplaceable resources. Whether humans can radically change their behaviour on a sufficient scale to prevent an environmental crisis remains to be seen.



**Dr Sandra Brooke**  
Florida State University Coastal  
and Marine Lab  
Tel: +1 850 697 4093  
sbrooke@fsu.edu  
<https://marinelab.fsu.edu/>

# Biofouling: Aliens in the Baltic Sea

Dominik Littfass, HELCOM Communication Secretary explains the biofouling – the attachment of living organisms to the hull of ships – one of the main vectors of invasions of aquatic ecosystems from alien or non-indigenous species

**B**iofouling – the attachment of living organisms to the hull of ships – is one of the main vectors of invasions of aquatic ecosystems from alien or non-indigenous species (NIS). Largely due to a global increase in international maritime traffic, biofouling is estimated to be responsible for more than half of coastal and estuarine species invasions worldwide.

In the Baltic Sea, NIS pose a serious threat. Compared to other seas, the Baltic's ecosystem is rather fragile due to its semi-enclosed nature and relatively low amount of species. As shown with the round goby, a fish thought to be introduced through ship ballast water from the Ponto-Caspian region, the introduction of alien species can lead to irreversible changes in the marine environment.

"It is extremely difficult to remove non-indigenous species from an aquatic environment," says Marta Ruiz, HELCOM expert on biofouling, adding that once species have settled in and start to take over a new habitat, there are almost no possibilities to revert their introduction. "Once there, these species are bound to stay."

Aggressive, territorial and voracious, the round goby is now found in all Baltic Sea sub-basins and is continuously increasing its range and abundance in recently colonised habitats, posing a strong predatory pressure essentially on epibenthic molluscs such as clams, mussels and other bivalves.

"The best way to deal with alien species is prevention, to ensure that they don't enter and colonise other habitats," advocates Ruiz. "One major vector of the introduction of NIS, ballast water from ships, is already being regulated. But there still is an urgent need to address biofouling."

Contrary to the management of ship ballast water which is regulated by the IMO's [Ballast Water Management Convention](#) (BWMC), which entered into force in 2017, biofouling is currently not controlled. Despite the IMO having issued guidelines on biofouling, there are no international regulations, with the exception of some local regulations such as in New Zealand or California.

But addressing biofouling isn't easy and not just because of missing regulations. Many anti-fouling systems that have proven to keep hulls clear contain biocides that aren't safe for the environment. For example, Tributyltin (TBT), which was widely used in ship paints for its biocide action, has shown to remain in the food chain for long periods of time and to disrupt the hormonal balance of living marine organisms.

The use of TBT has, therefore, been banned and other key biocides are currently being assessed and might face a similar fate. This lack of options makes biofouling management more difficult. On the other hand, having a clean hull is a benefit also to ship owners due to reduced drag, translating into increased energy efficiency, less fuel consumption and fewer emissions of exhaust gases.

In the Baltic Sea, addressing biofouling and the introduction of NIS follows a deeper agenda. The Baltic Sea is not in a good state, currently affected by a wide array of pressures such as eutrophication, hazardous substances, overfishing or the effects of climate change. Recent assessments have shown that recovery might take several decades for eutrophication alone. To give the fragile ecosystem a chance to deal with the long-term pressures, addressing the ones that are within reach should be a strategy to follow.

In its [Baltic Sea Action Plan](#) (BSAP) – the regional strategic





*Sailing ships on the Baltic Sea in Rostock (Germany)*

Image: © Ricok | Dreamstime.com

programme for a healthy Baltic Sea – HELCOM has already formulated a management objective of “No new introductions of non-indigenous species”, echoing the EU’s [Marine Strategy Framework Directive \(MSFD\)](#) on the same topic. The BSAP is bound to be updated by 2021 and NIS are already one of the focus points. It is expected that biofouling will prominently feature in the updated plan.

HELCOM also closely monitors the introduction of new species through a dedicated indicator on NIS. In total, about 140 alien species have been recorded in the Baltic Sea to date.

Furthermore, to advance the agenda on biofouling in the Baltic Sea and help the formulation of a harmonized regional policy response, the EU-financed Interreg platform launched the [COMPLETE project](#), of which HELCOM is part. COMPLETE currently looks into methods to keep ship hulls clean, as well as into benefits of hull cleaning on ship fuel consumption and emissions. A regional biofouling management strategy for the Baltic Sea will also be developed as part of the project.

Nevertheless, when it comes to dealing with the introduction of alien species to the marine environment, there still is a major gap between the stringent rules for ballast water management and the lack of regula-

tions on biofouling. To prevent unwanted introductions of NIS to the Baltic Sea, that gap needs to be closed with clear rules on biofouling too.

### About HELCOM

The Baltic Marine Environment Protection Commission – also known as the Helsinki Commission (HELCOM) – is an intergovernmental organization (IGO) and a Regional Sea Convention in the Baltic Sea, consisting of 10 Contracting Parties: the nine Baltic Sea countries Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden, plus the European Union. A true platform for policy-science interaction at the regional level, HELCOM works for a healthy Baltic Sea. Its mandate stems from a regional treaty, the Helsinki Convention, whose implementation it oversees. The HELCOM Secretariat is located in Helsinki, Finland. ■

#### Dominik Littfass

##### HELCOM Communication Secretary

Baltic Marine Environment Protection Commission –

Helsinki Commission (HELCOM)

[dominik.littfass@helcom.fi](mailto:dominik.littfass@helcom.fi)

[www.helcom.fi](http://www.helcom.fi)

[www.twitter.com/helcominfo](https://www.twitter.com/helcominfo)

# Environmental approaches to regional security

Juri Martin from EuroAcademy offers his expert thoughts on environmental approaches to regional security

In many regions of the world, the renewable natural resources are being utilised faster than their natural rate of renewal and the regional environment is being abused in many other important ways as well. Moreover, the ecogeographical regions (ecoregions, regional approach, spatial planning) of the world are not generally delimited in synchrony with the political boundaries of the world.

## The concept of environmental security

Two major prerequisites must be satisfied to achieve environmental security:

- A *protection requirement*, that is, the quality of the human environment must be safeguarded;
- A *utilisation requirement*, that is, any exploitation (harvesting or use) of renewable natural resources must be carried out on a sustaining basis.

The problems associated with environmental security fall into a number of more or less distinct categories and sub-categories:

### 1. Problems associated with the protection and conservation of the environment:

- Avoidance of vandalism (wartime or other non-remunerative destruction);
- Avoidance of excessive pollution, that is, pollution in excess of the natural renewal or cleansing processes and;

- Avoidance of any permanent anthropogenic intrusion whatsoever in a modest number of special areas.

### 2. Problems associated with utilisation of the environment (ecosystem services):

- Avoidance of utilisation at rates beyond long-term sustainability, that is, in excess of maximum sustained yield or maximum sustained discard and;
- Avoidance of utilisation – in the event of past abuses – at rates that will prevent recovery of the degraded environment (recovery, moreover, that may well require human assistance).

The problems associated with environmental protection, conservation and utilisation will, of course, vary in detail depending upon the nature of the resource. Resources can conveniently be divided into the following categories:

- **Non-extractive resources**, including the land and its soil, water and the atmosphere and;
- **Extractive resources**, including non-renewable resources and renewable resources.

It must be stressed that all utilisation of the renewable natural resources must be carried out on a sustained-yield basis; and that all disposal of waste must be carried out on a sustained-discard basis (circular economy). Without

an inflexible commitment to the sustainable development of resources and the sustainable disposal of waste, there can be no environmental security.

**“It must be stressed that all utilisation of the renewable natural resources must be carried out on a sustained-yield basis; and that all disposal of waste must be carried out on a sustained-discard basis (circular economy).”**

Protecting the quality of the human environment implies the prevention of soil erosion, of air pollution and of water pollution in excess of levels that would jeopardise the public health. It further implies the maintenance of representative habitats in their natural state and the prevention of species extinctions. In those instances where environmental damage or deterioration of some sort is already prevalent, the protection of the human environment implies actions that would restore the damage, at least in so far as this remains possible.

 **EUROAKADEEMIA**  
[www.euroakadeemia.ee](http://www.euroakadeemia.ee)

**Mr Juri Martin**

EuroAcademy

<http://euroakadeemia.ee/en/>



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# Systems approaches: Making pests run a gauntlet to safeguard crops and forests

Greg Rosenthal of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service details the importance of the multiple safeguards in systems approaches – when it comes to making pests run a gauntlet to safeguard crops and forests

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) views global agricultural trade through a plant health lens. The challenge, from this perspective, is how to move billions of dollars' worth of agricultural products across the world's oceans and continents without spreading invasive plant pests. APHIS recognises systems approaches as powerful tools to meet this challenge. A systems approach is a series of measures taken by growers, packers and shippers that, in combination, minimise pest risks prior to importation into the United States.

## Systems approaches

Under a systems approach, different steps of the production chain provide opportunities to reduce risks from pests—from pre-planting, pre-harvest, during the growing season, through harvest, to the packing house, to the exporting country's port, to the importing country's port of entry, and into domestic commerce. The idea is to apply enough measures that together ensure an appropriate level of protection.

Examples of these measures include, among many others: sterilising soil for pests; using only certified seeds for planting; surveying for insects; inspecting and treating crops; sanitising equipment moving between fields; harvesting before pest risks emerge; employing pest-proof structures; inspecting, cleaning, and disinfecting commodities at packing houses; placing commodities in pest-proof packaging; conducting cold treatments in transit; inspecting commodities at the port of entry; and establishing end-use restrictions, such as human consumption versus animal consump-

tion versus planting, flour milling only for certain grains, or juicing only for certain fruits.

Countries around the world are using and mutually recognising systems approaches as a way to facilitate safe trade. The International Plant Protection Convention (IPPC) formally adopted the concept in 2002. The IPPC is an international agreement among 183 countries, including the United States. It provides the world with plant health standards and critical tools, such as systems approaches, for negotiating technically sound international trade requirements. The U.S. Plant Protection Act of 2000 defines systems approaches for APHIS.

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**“Systems approaches like this one help make global trade safe, fair, and predictable. For imports and exports, they are here to stay.”**

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## Benefits of systems approaches

Systems approaches have many advantages. They can work when a single pest mitigation measure will not be effective or feasible. This is particularly important now that, because of human health and environmental concerns, many countries discourage the use of methyl bromide—traditionally a single and extremely effective measure. In addition, if one measure fails in a systems approach, the remaining measures provide redundancy to ensure an appropriate level of protection.

For example, U.S. imports of bell pepper from Spain are allowed under a systems approach that includes production in pest-proof greenhouses, registration and oversight by Spanish agricultural department authorities, regular greenhouse inspections and pest

monitoring, pepper packing requirements, and use of insect-proof covering for transit to the United States.

In addition, two APHIS programs certify exports to and allow imported nursery stock from Canada under systems approaches. These programs promote trade consistency between our two countries. APHIS also accepts imported plant cuttings grown under systems approaches from APHIS-certified foreign facilities producing these commodities.

Systems approaches can leverage the industry's current best practices. That means growers can address pest concerns in a way that doesn't add burdensome requirements. Because participants across a supply chain take steps to address pest concerns before a commodity ships to the importing country, systems approaches can also facilitate the smooth entry of commodities into the importing country.

### **Taking systems approaches a step further**

Over time, APHIS' experts observed that many import requests for plants in growing media (PIGM) were very similar to each other. They realised this similarity offered an opportunity to streamline how they evaluate and process many of these import requests. Normally, APHIS prepares an environmental assessment (EA) unique to each country's request for a specific plant genus in growing media, such as peat or coal cinder. The EA assesses the potential environmental consequences of the proposed importation. We also prepare a pest risk assessment (PRA) to identify the risks, and a risk mitigation document (RMD) to identify measures to help prevent the entry of pests on the plants.

For most requests, those measures – a systems approach – are identical, although we add specific measures as needed. As a result, we determined that a single programmatic EA could apply to most PIGM import requests. That would reduce the need for repetitive documentation of comparable risks. However, if the PRA and the RMD for a routine request identifies new risks for consideration, APHIS would prepare an environmental document. And if we detect a quarantine pest in imported PIGM, we would stop importing that plant from that country until current or revised pest mitigation measures are shown to be effective.

Using a single programmatic EA would ensure continued levels of safeguarding while facilitating international trade, allowing healthier plant imports, reducing the growing time for plants to reach markets, reducing unnecessary or repetitive environmental and other documentation, and speeding port-of-entry inspections.

On 10th April, we published a draft programmatic EA in the U.S. government's newspaper of record, the Federal Register, and are accepting public comments until June 24, 2019. Once a final decision is made regarding the issues within the EA, that EA will cover all future PIGM import requests that use only the default systems approach measures. If a particular import request requires additional measures, we will prepare another environmental document that evaluates those measures. The required documentation will depend on the type and magnitude of risk from the additional measures.

### **The two sides of systems approaches**

APHIS regularly authorises imports of fruits, vegetables, nursery stock, and other agricultural commodities under a systems approach. We also negotiate the use of systems approaches with our trading partners when they consider U.S. requests to export commodities to their markets. For example, our cherry exports to Japan must comply with a systems approach that includes, among other measures, orchard registration with APHIS, pest trap use, specific inspection and processing procedures at the packing house, carton labelling, and inspection upon arrival in Japan.

Systems approaches like this one help make global trade safe, fair, and predictable. For imports and exports, they are here to stay. ■

#### **Greg Rosenthal**

##### **Communications Specialist**

United States Department of Agriculture (USDA)

Animal and Plant Health Inspection Service

[www.aphis.usda.gov/aphis/home](http://www.aphis.usda.gov/aphis/home)

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# Building better oaks for the urban environment

Dr Nina Bassuk, Urban Horticulture Institute, School of Integrative Plant Science explores how building better oaks will help improve the future of urban environments

The oak genus (*Quercus*) has over 500 species of trees and shrubs native to regions across the northern hemisphere. It is difficult to overstate their ecological, economic and cultural value. Oaks provide an essential source of timber for furniture, flooring, interior finishing and veneer. Cork is sourced from oak and the impervious heartwood of oak is used for shipbuilding and wine and whiskey casks. Oaks are prominent in many forest ecosystems and their acorns are a vital food source for wildlife, high in fat and nutrients.

In addition, oaks have an important role to play in urban and suburban landscapes as they are durable, long-lived and majestic trees. They can be an outstanding feature in any park with a large and spreading growth habit. The grand size, longevity and sturdiness of oaks have made them a familiar symbol in many cultures around the world.

## Genetic diversity of oaks

Even within a species, oaks exhibit wide variability in phenotypic traits, e.g. leaf size, shape and colour. Furthermore, oaks are found in many different climates throughout the northern hemisphere. They range from the humid, sub-tropical regions of Central America or Asia to the semi-arid terrain of California or the Mediterranean and to the furthest reaches of deciduous forest in the north.



*Oak shoots multiplying in tissue culture*

The genus *Quercus* is divided into two subgenera: *Cyclobalanopsis* and *Quercus*. The latter is then subdivided further into four sections: *Protobalanus*, *Cerris*, *Quercus* (white oaks) and *Rubrae* (red oaks). The section *Rubrae* includes many red oaks with which we are familiar e.g. *Q. rubrum* (red oak), *Q. velutina* (black oak) and *Q. palustris* (pin oak). The section *Quercus* includes species of white oak familiar in northern climates such as *Q. robur* (English oak), *Q. alba* (white oak), *Q. bicolor* (swamp white oak) and *Q. montana* (chestnut oak). Oaks readily hybridise between species within their respective sections and intermediates are often found within overlapping geographic ranges.

The number of species counted within the genus *Quercus* contained around 300 in 1862 compared to over 500 species counted in 1998). Although

interspecific hybrids are not immediately considered a new species, this shows the complexity of delineating species within the genus. Oaks are often discussed in many studies on plant evolution and speciation because of their ability to hybridise.

Within just the white oak section, species are found growing from Cuba to central Mexico to Northern Canada, making the genetic potential of this group appealing. For example, species within this group found in the northern latitudes have cold tolerance while those growing in southern regions like *Q. virginiana* (live oak) show incredible drought and wet soil tolerance. *Q. bicolor* is native to the northeast and tolerant of heavy, compacted soils, while *Q. minima* (dwarf live oak) grows along coasts and shows salt tolerance. Therefore, the wide variety of traits in white oaks, as





*Rooted oak from tissues culture*

well as their interspecific hybridisation, makes them a desirable group for selection for growth in urban environments.

### Selecting oaks for the urban environment

Trees growing in an urban setting face distinct challenges from trees growing in the wild. These challenges include limited soil volume, soil compaction, road/sidewalk salt, soils with high pH and drought stress. Many native oaks are sensitive to alkaline soils because important nutrients (especially iron and manganese) become less soluble and available for absorption by plant roots at a pH higher than 7.0. This nutrient deficiency results in chlorosis (yellow leaves). Unfortunately, alkalinity is a frequent characteristic of many urban soils.

At Cornell University's Urban Horticulture Institute, (UHI) hybrids between many different species of white oak were created between 2004-2006. The maternal species were located on the Cornell campus in Ithaca, New York and include several native and purported hybrid white oaks:

- *Quercus bicolor*
- *Quercus gambelii* x *macrocarpa*

- *Quercus macrocarpa*
- *Quercus macrocarpa* 'Ashworth'
- *Quercus montana*
- *Quercus muehlenbergii*
- *Quercus x warei* 'Long' (Regal Prince®).

Pollen from approximately 40 different species from Europe, Asia and North America were used for hybridisation. Some of the paternal species include *Q. virginiana* (live oak), *Q. lyrata* (overcup oak), *Q. robur* (English oak), *Q. fusiformis* (Texas live oak), *Q. polymorpha* (Mexican White Oak). As a result of the breeding programme over 350 unique hybrid genotypes were developed. Over the years these hybrids have been evaluated for tolerance to cold temperatures, drought and high pH soils. We have also evaluated their overall growth habit and form and we noted any issues with pests or diseases. Many hybrid trees showed good form and vigor.

### Oak selection and propagation research

Another aspect of this project involves propagation research. Oaks are notoriously difficult to propagate asexually. Once hybrids are created, they must be propagated asexually in

order to maintain hybrid characteristics. Using acorns for propagation would negate the hybrid qualities due to pollination by nearby oaks. Difficulty in asexual propagation impedes the selection of hybrids, as it is difficult to propagate clones of each genotype for testing in the field.

Therefore, as we evaluate our hybrid genotypes for desirable growth characteristics, we also consider whether it is possible to propagate them asexually. To introduce a superior tree into the nursery trade, we need to be able to propagate it in large numbers.

So far, propagation approaches have included the use of modified stool beds and tissue culture. By using very small expanding buds, we are able to grow many hybrid oaks in tissue culture, which has the potential of rapidly increasing our numbers to that these trees can be introduced to the nursery trade. This work has taken over 25 years is the result of many researchers improving our understanding of these hybrids over the years. We are confident that we may have some superior urban tolerant oaks to introduce in the near future.



Cornell University

#### Dr Nina Bassuk Professor

Urban Horticulture Institute,  
School of Integrative Plant Science  
Cornell University, New York, U.S.  
Tel: +1 607 255 4586  
nlb2@cornell.edu  
<https://blogs.cornell.edu/urbanhort/>

*The Urban Horticulture Institute  
Nina Bassuk, Bryan Denig, Anne Johnson,  
Miles Schwartz-Sax*

# The value of plant science in Europe today

The European Plant Science Organisation (EPSO) reveals its thoughts on the value of plant science and the many improvements it can generate in areas such as sustainable agriculture, forestry and environmental conservation

Plant science can generate improvements in sustainable agriculture, forestry, environmental conservation, biodiversity protection and climate action, as well as in the production of nutritious food and plant-based non-food products – such as paper, timber, chemicals, energy and pharmaceuticals. In addition, plant research has the ability to advance other branches of science. Mendel's law (a core of classical genetics and inheritance) and gene silencing (utilised in medicine and broadly used in research) are only two of numerous examples of contributions of plant science to biology. Sadly, plants are still largely underappreciated.

The European Plant Science Organisation (EPSO) aims to improve the impact and visibility of plant science in Europe. Its top priorities are to coordinate research activities at the national and European levels and beyond, to facilitate the understanding of plant science, and to provide advice on science policy towards a strategic approach and critical mass funding for basic and applied research.

EPSO hosts international conferences for plant scientists to promote networking and facilitate collaboration across countries and disciplines, which is key to advancing scientific research. Another important component of EPSO is its international Working Groups that bring together experts in different areas of research to generate shared learning, ensure best practice and build consensus on policy positions. They further consider how the knowledge generated by EPSO researchers can contribute to the society. For instance, the Agricultural Technologies Working Group focuses on science contributions to plant breeding sector, with a growing number of human population and changing environment being at the forefront of challenges of modern agriculture.

We believe that basic plant research can fuel innovations useful to the society, such as innovations within sustainable plant breeding sector. One of the persisting problems threatening the fields are pests and plant diseases, which often require extensive sprays (with pesticides, fungicides, etc.) to manage. Plant scientists





across Europe and beyond have been looking for solutions to tackle this problem. To date, dozens of plant disease resistance genes against pathogens have been identified, all of which can be utilised in the field to reduce yield loss and spray use. Successful examples include resistance against devastating rice blast and potato late blight diseases, to name just a few. Likewise, understanding basic plant developmental or biochemistry processes can help in generating plants that produce a higher yield or are free from common plant allergens, such as gluten.

Notably, plant science provides critical research insights that can help inform innovations and policies that affect all areas of our lives and thus all 17 of the 2016 UN Sustainable Development Goals (SDGs). Plant science has the power to restore lost diversity among crops leading to higher yield with a lower environmental footprint, and resilience to extreme environmental conditions, such as adverse soil conditions and higher nutritional value – all of which support the ambition for Zero Hunger (SDG2) and Good Health and Wellbeing (SDG3). Evaluating the capacity of soils and forests to absorb carbon and, subsequently, limit global warming can enhance Climate Action, SDG 13. Monitoring the effects of the exploitation of natural resources and habitat degradation on biodiversity can help inform policies on sustainable resource use, which contributes to the success of SDGs 14 and 15, Life Below Water and Life on Land, respectively.

Yet to conduct cutting-edge research and achieve those goals scientists need investment. Sadly, plant research has been massively underfunded compared to other science disciplines, with plant research proposals often being overlooked. More equal funding would generate greater overall benefits for society. EPSO promotes plant science and campaigns for a higher appreciation of the value of plant research among funding bodies.

We are also dedicated to popularising plant science among the general public. Through public engagement events, we aim to raise awareness of the relevance of plants to health, the environment and the global economy and to improve public understanding (and correct misconceptions) on topics such as new breeding technologies and gene editing. We also hope to attract young curious minds to pursue a career in plant research in the future. With these aims, EPSO organises a biennial Fascination of Plants Day (FoPD) – a worldwide public engagement initiative in which volunteers run local and national community events celebrating plants and plant science. In addition, EPSO further advocates for evidence-based and plant science-friendly policies through its EPSO and FoPD social media accounts, which collectively cover both lay and expert audiences.

We believe that public engagement is a key part of research dissemination that enhances public understanding of plant science and improves the dialogue between researchers and the public. It is crucial for the future funding of their research that plant scientists communicate the value of their work for the daily lives of people. We hope that as people and funding bodies better appreciate the benefits of plant science, funding for it will increase.

EPSO currently brings together more than 200 research institutes, departments and universities from 30 countries in Europe and beyond, and Fascination of Plants Day hosts over 1000 public engagement events across 51 countries. Over the years, we have been able to establish collaborations that led to ground-breaking discoveries and improved impact and visibility of plant science. We will continue this international cooperation to further advance plant science and ensure that the opportunity cost to society of better investing in plant science is not lost. ■



**Carmel Edwards, Publications Officer**  
**Aleksandra Bialas, Policy & Comms Assistant**

European Plant Science Organisation (EPSO)

Tel: +32 2 213 62 60

[epso@epsomail.org](mailto:epso@epsomail.org)

[www.epsoweb.org](http://www.epsoweb.org)

@EPSOEurope



# Plant-plant communication for sustainable pest management

Velemir Ninkovic, Associate Professor at the Swedish University of Agricultural Sciences (SLU), explores plant-plant communication for sustainable pest management

Our society and farmers are in the need of knowledge and tools required to maximise ecosystem services for the production of crops while minimising the environmental impacts of agriculture and ensuring the profitability of farming. Our research aims to provide new strategies for plant protection whilst improving our insight into the world of plant-plant communication.

## Why do plants communicate with each other?

Plants live in a crowded environment surrounded by other plants from the same or different species. Coexistence with other neighbouring plants is constant and include competition for the same available resources during their life span. As a consequence of their sessile lives, plants can't fly away from their competitors and other treats, instead they directly dependent on their sensitivity and have the ability to respond to challenges in a timely manner. To set face against a potential competitor, every individual plant has to monitor surrounding cues and detect those pointing on an upcoming treat.

Permanent exposure to diverse cues makes an appropriate plant response even more difficult, as they have to distinguish important cues from insignificant ones. Among the cues that every plant may perceive, volatile organic compounds (VOCs) constantly released by neighbours are one of the most reliable. The information

available to the plant through the interpretation of VOCs can help it to adapt to specific neighbours as they provide unique information about the physiological status of the emitter. Those cues may also contain elicitors of defence responses in plants. Based on the type of cues perceived plant can then react to compete when necessary or avoid unfavourable competition.

## The role of the volatile communication between undamaged plants

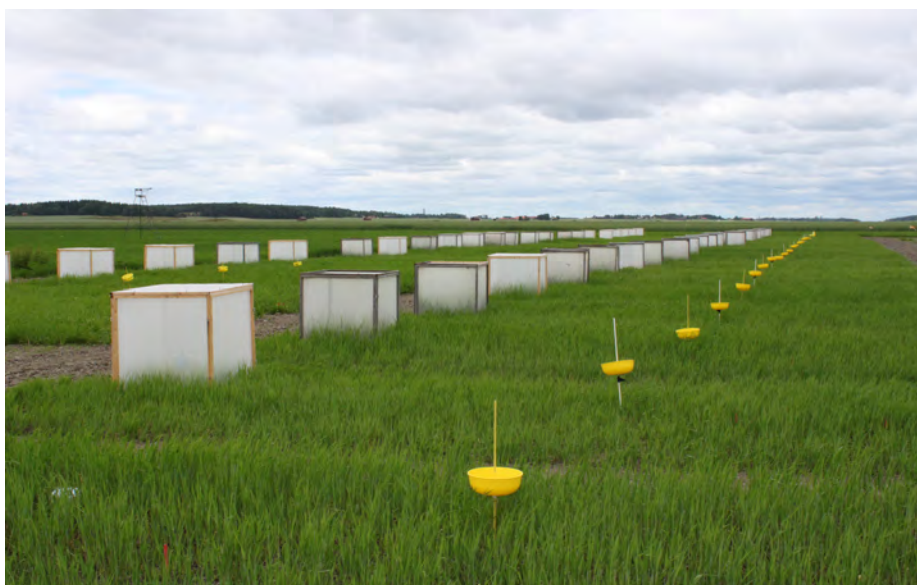
We are studying volatile interactions between undamaged plants and their potential ecological significance. In particular, we focus on volatile interactions among different genotypes of the same plant species and their effect not only on direct competition but also as a source of information that can be used to adapt to upcoming events.

Volatile profiles are genotype-dependent and differ between cultivars of the same plant species, indicating that exposure effects can occur only in certain cultivar combinations. Depending on the type of volatile cues received, exposed plants show specific responses that include physiological and morphological changes such as biomass allocation, shade avoidance and volatile emission. For instance, under normal light conditions, exposure to volatiles from one barley cultivar induces biomass allocation to the

roots in another cultivar. In the same cultivar combination, when only emitter plants were exposed to low light conditions, they released less VOCs that affected exposed plants to allocate more biomass to the shoots. We have also shown that volatile interaction between plants of different species can induce changes in the volatile profile of exposed plants making them less attracted to herbivore insects.

Plants are not interacting by VOCs only with each other but also with other organisms at higher trophic levels. Those changes in VOCs have further implications on herbivore insects as they elicit natural defence in exposed plants and, thus, reduce their acceptability. However, VOCs induced plant responses to insect pest suppression occur only in specific combinations of plant species. The advantage of increased within species diversity is that plants are already induced when migrant aphids arrive and attempt to settle in the crop.

We have observed a significant reduction of aphid attack both in the lab and field and an increase in the yield only in specific combinations of plant genotypes and species. Volatile cues from responding genotypes can attract aphid predators, such as ladybirds when searching for favourable food sources. Taken together, the results from our studies suggest that plant-plant communications change olfactory



*A field experiment with volatile communication between different barley genotypes, testing induced changes in the plants and their influences on the occurrence of aphids and their natural enemies*

cues of diversified plant stands which is an important underlying mechanism in predator attraction to sites with a complex botanical diversity, which can be utilised in the development of sustainable pest management.

## Plant communication by touching

Mechanical contact with other plants is another early detections cue that reveals the actual presence of competitive neighbour and induces changes in their establishment strategy. We have tested plant response to touch and demonstrated that touch may have a potential role in the detection of neighbouring plants and may affect plant-insect interactions. Our results show that one minute of touching per day can induce changes in biomass allocation and increase trichome production via a systemic effect. Plants response to touch also induced changes in the blend of volatile organic compounds released what resulted in the reduced olfactory attraction of insect herbivores and ladybirds, their natural enemies.

Exposure to touch-induced volatiles has demonstrated an important ecological role as these cues are directly involved in plant-plant communication as an effective trigger for rapid defence in nearby plants. Perception of those VOCs induces activation of same defence-related genes in non-touched neighbouring plants, showing a mirroring effect in the expression of specific genes upregulated by touch. Such coordinated defence responses significantly reduced aphid acceptance on both touched and exposed plants.

These examples show the potential of volatile plant interactions and mechanical contact to induce direct plant defences against herbivores or indirect through biological control, which can be a promising strategy for the development of sustainable cropping systems. It is becoming obvious that the application of plant signals in sustainable agriculture has great potential as they demonstrate to modify plant metabolism and affect the behaviour of herbivore insects. However, there is a need for more

detailed knowledge that will contribute to fine-tuning sustainable pest management from an environmental, social and economic perspective.

## Plant communication in the practice

To go even further within the European H2020 EcoStack project, we are now testing the effect of within-species plant-plant communication and other ecosystem services on insect pest occurrence and population development. When we utilise this knowledge, we can improve pest management in a sustainable way, increase biodiversity and reduced pesticides usage. We can take advantage of the already existing natural defence capacities of our crops and put them into the function. Ultimately, together with EcoStack, we will provide a range of sustainable practices for future agricultural strategies in Europe.



**Velemir Ninkovic**  
Associate Professor  
Swedish University of Agricultural Sciences (SLU)  
Tel: +46 18 67 25 41  
[velemir.ninkovic@slu.se](mailto:velemir.ninkovic@slu.se)  
[www.slu.se/ninkovic-lab](http://www.slu.se/ninkovic-lab)  
[www.twitter.com/LabNinkovic](https://twitter.com/LabNinkovic)

# The popular potato crop and the major threat of blight (early and late)

Aarthi Janakiraman, Industry Manager, Chemicals and Advanced Materials at TechVision, Frost & Sullivan, shares her thoughts on the popular potato crop, as well as the potato blight (both early and late) which remains a major threat to production

Potato is currently ranked fourth among the staple food crops after maize, rice and wheat. Its short growing cycle and climatic adaptability have made it into a crop that is spread geographically from its South American origin, with Europe and UK still prominent despite increasing participation of growing economies, such as China and India. Despite varying opinions towards its health benefits and nutritive value, it can't be denied that the crop is highly marketable, be it as a raw tuber or in the form of processed food products, animal feed ingredient, even as feedstock for biofuel generation. Its global importance is non-debatable and so is its role in overcoming food shortage issues.

Despite differences between the potato industry in Europe and UK, especially towards the intended market for the crops, (European nations tend to focus more on the processing industry), challenging planting conditions, health of the crops due to possible droughts and diseases are the key concerns of growers, be it in European mainland or the UK. The last two to three seasons have seen fluctuations in production, pricing and even arable land. Apart from the usual suspects of harsh growing conditions and fieldwork difficulties, the influence of climate change can no longer be denied and its effects esp. towards availability of ample water to irrigate are to be felt in the 2019 growing season.

Potato blight (both early and late) remains the major threat to production, with worldwide crop losses estimated to be in excess of £3.5 billion. Studies have indicated that farm blight management can account for as much as half of the total cost of potato production. The possible adverse effects combined with already challenging conditions has made it imperative for

growers not only to control but also prevent blight occurrence. The current fungicides are effective for a shorter span of time and growers incur not only the economic cost but also environmental costs. However, the use of locally systemic and translaminar fungicides is still necessary for control of blight. Identification of blight strains resistant to fungicides is a high possibility and this year has seen two blight strains, 37\_A2 and 36\_A2, being confined not only to the UK.

This scenario has established the need for careful selection and rotation of fungicides with varying modes of action and also prevents early blight from building further resistance. The importance of integrated disease and pest management solutions are required to provide growers not only details about weather forecast conditions, but also information about disease prevention and intervention. Real-time sensing and monitoring that will provide data about localised conditions and other factors, such as irrigation can be integrated with weather forecasting models to provide a holistic real-time model to predict blight occurrence.

Various research studies are underway that explores various methods to address the blight issue. Apart from developing effective fungicides, the feasibility of introducing genetic resistance to crops is being explored. There are many challenges to address, especially the deployment of genetic resistance using conventional breeding techniques. While still in nascent stages, the approach, if fruitful, can reduce the need for commercial spraying. Also, sources of resistant genes are also difficult to find; researchers are also investigating the development of viable real-time sequencing techniques.





With the processed food industry already focused on food safety and ensuring “clean label”, addressing challenges during production and storage can close the loop and help to ensure the growth of the potato industry. Closer working relationship with all stakeholders, right from growers to academia and industry associations to companies across the value chain can help in not only providing a platform to address challenges and explore solutions but also help in testing and rapid deployment of the same. ■

## Acknowledgement

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The industry should also focus on improving soil health to ensure nutrient bioavailability and minimise the effects of drought and salinity. Post-harvest storage conditions also need to be prioritised, as it not only to reduce crop losses but also plays a significant role in determining end-product processing quality. Initiatives such as that of AHDB’s one-to-one storage advice can go a long way in minimising storage losses.

Research initiatives are also focused on increasing the nutritional quality of potatoes, especially protein, vitamin, phenolic and carotenoids content and even though no major anti-nutrient contents are being reported, reduction of the percentage of steroidal glycoalkaloids (SGAs) is also of interest. CRISPR/Cas9, TALENs and ZFNs can help expedite gene editing of the tuber and offer precision while saving time. Knowledge about the genome sequence will facilitate in identifying genes that are useful for improving agronomic traits, nutritive value and enhance disease resistance.

## Aarthi Janakiraman

### Industry Manager, Chemicals and Advanced Materials

TechVision, Frost & Sullivan

Tel: +91 44 6681 4102

[aarthij@frost.com](mailto:aarthij@frost.com)

[ww2.frost.com](http://ww2.frost.com)

[www.twitter.com/Frost\\_Sullivan](https://www.twitter.com/Frost_Sullivan)

# Understanding the potato late blight pathogen: Key for sustainable control

Didier Andrivon from INRA details why an intimate knowledge and understanding of the potato late blight pathogen and its evolution are key towards sustainable control

**P***hytophthora infestans*, the causal pathogen of potato late blight, is known to be a versatile enemy. Its ability to constantly generate new variants is certainly one of the main assets of this highly epidemic parasite for causing recurring threats on potato and tomato crops worldwide.

The recent EuroBlight workshop, held in York (UK) from 12th to 15th May 2019, once again highlighted the new emergences of clonal lineages of *P. infestans* going on in Europe, and reflected on their immediate and longer-term consequences for sustainable management of the disease. It also shed further light on global migrations of European lineages and on the issues these pose for blight control globally.

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**“Such intra clonal selection needs to be better documented and quantified, so it can be integrated into population dynamics models to simulate invasive dynamics more accurately, according to local competitors, environmental conditions and the resistance features of host cultivars.”**

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## Ongoing changes in European *P. infestans* populations...

As yet rare genotypes EU\_36\_A2 and EU\_37\_A2, first spotted in the northern part of the Netherlands in 2013/2014, started spreading over north-western Europe from 2016, and replaced earlier



Late blight disease on a potato leaf

lineages, such as EU\_13\_A2 and EU\_6\_A1 there. Meanwhile, genotype EU\_41\_A2 established itself in sexual, Nordic populations over the past three years (Figure).

The precise reasons for such rapid population invasions are yet to be fully elucidated, but some phenotypic characteristics of the newcomers are probably part of the equation. Indeed, recent reports confirmed that genotype EU\_37\_A2 is insensitive to fluazinam, a major late blight fungicide. Investigations made within the frame of the European project IPMBlight2.0 also indicated that genotype EU\_36\_A2 was among the most aggressive of current populations and that genotype EU\_41\_A2 had the ability to overcome many race-specific resistance genes available to breeders or present in current potato cultivars.

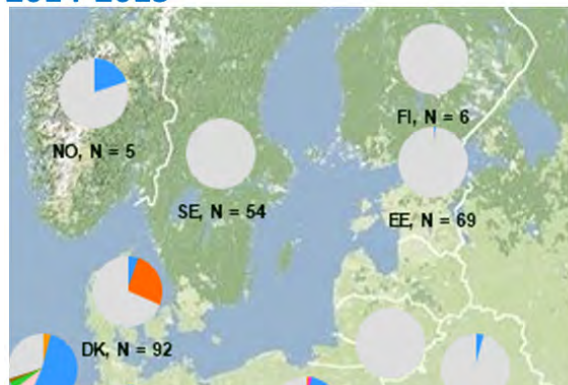
Despite these advances and new, quantitative data on major phenotypic traits and their distributions across genotypes and geographical areas, our scientific community still lacks some critical information to turn population information into an asset for predictive management of blight outbreaks and emergencies. In particular, the elusive connection between genotypic and phenotypic variation in *P. infestans* and the impossibility to correctly quantify the response of pathogen populations to selection for want of accurate, geo-referenced databases on fungicide and cultivar distribution, leave many tentative explanations for the rapid changes observed in population structures untested.

## ...but also worldwide

The same methodologies were also



## 2014-2015



## 2016-2018

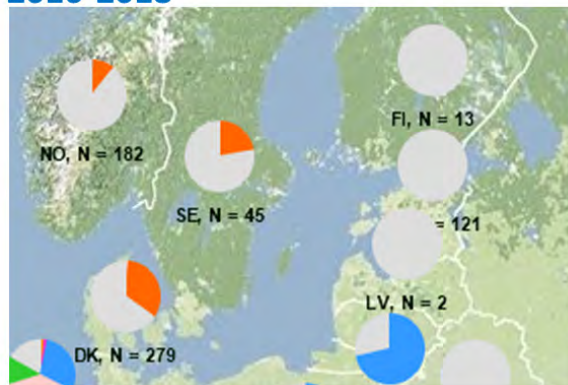


Figure: Recent changes in the genetic structure of Nordic *Phytophthora infestans* populations. The maps show the invasive dynamics of the clonal lineage EU\_41\_A2 (orange sectors of the pie charts) in Denmark, Norway and Sweden over the past three years. This invasion is remarkable since it occurs in populations made of a multitude of unique genotypes (labelled 'other', grey sectors of the pie charts), presumed to be of sexual origin and assumed to make these populations less vulnerable to invasion. Data - Euroblight.net

successfully applied to track the recent spread of more ancient European *P. infestans* genotypes over their worldwide expansion. Of particular significance are the recent discoveries of the presence of genotype EU\_2\_A1 in Latin America, eastern Asia or eastern sub-Saharan Africa with major consequences for control efficacy.

**“Its ability to constantly generate new variants is certainly one of the main assets of this highly epidemic parasite for causing recurring threats on potato and tomato crops worldwide.”**

The main question open now is ‘what makes different clonal lineages invasive in different environments’? The phenotypic traits measured in the lab are only part of the answer, for two reasons. First, they are measured under optimal conditions for the pathogen – which are not constantly present in the field. Therefore, pathogenicity data under sub-optimal environmental conditions would be needed for a better prediction of pathogen fitness in the field. However, acquiring such data is technically challenging and time-consuming, explaining why they are currently so scant. Second, the laboratory tests reveal extensive variation not only between

lineages but also among individuals belonging to the same lineage. This intra-clone variation, therefore, allows selection of more or less pathogenic within each clonal lineage, without affecting the balance between lineages in the general population. Such intra clonal selection needs to be better documented and quantified, so it can be integrated into population dynamics models to simulate invasive dynamics more accurately, according to local competitors, environmental conditions and the resistance features of host cultivars.

Such integrative models are currently under development. Because they are based on biological traits of the pathogen rather than on local cropping practices, they will apply to all types of potato production situation – conventional or organic, in developed as in developing countries. They will certainly help us turn population data into helpful tools not only to understand ongoing changes as they are monitored (for instance, via the Euroblight population surveys) but also to anticipate them to the advantage of growers. Indeed, they should be the key to better adjust the choice of cultivars, of field applications of fungicides or of biocontrol products

and the timing of these applications, depending on the local characteristics of pathogen populations present. This is the basis of IPM 2.0, a key to a more sustainable control of major diseases such as late blight.



**Didier Andrivon**  
**Research Director (Senior Scientist)**  
 INRA  
 Tel: +33 (0)223 485 193  
 Didier.Andrivon@inra.fr  
<https://www6.rennes.inra.fr/igepp>  
[www.twitter.com/AndrivonD](https://twitter.com/AndrivonD)



# Studying and advancing the field of plant pathology

The British Society for Plant Pathology's aims of studying and advancing the field of plant pathology are explored here, including the importance of advancing education in the field

The British Society for Plant Pathology (BSPP) began its life in 1981, with the clear aim of studying and advancing the field of plant pathology. Supporting the professional interests of plant pathologists globally is a key aim of the BSPP through a number of means, such as a newsletter. The BSPP has a board who meets four times a year when they develop and discuss new ideas and initiatives to support and promote plant pathologists.<sup>1</sup>

## Advancing plant pathology education

When it comes to education in the field, BSPP keenly believes in supporting GCSE and A-level units on communicable diseases of plants. This can be achieved by means of accessible and simple descriptions of the pathogens which have been reviewed by plant pathologists. For example, on the website of BSPP, we learn that plant Pathology can be described as: "The study of plants and their pathogens, the process of disease, and how plant health and disease are influenced by factors such as the weather, non-pathogenic microorganisms, and plant nutrition. It encompasses fundamental biology as well as applied agricultural sciences."<sup>2</sup>

The BSPP clearly supports the advancement of plant pathology education from primary school<sup>3</sup> to university level<sup>4</sup> but beyond, that they strongly support careers in the field. Certainly, there are a huge number of careers in the field and the majority of plant pathologists find their employment by doing government-funded research or working in university departments or for commercial companies. We know that such a person has an interest in, "understanding the organisms and agents that cause plant diseases and how diseases affect plant health."<sup>5</sup>

On the subject of education, we also know that the BSPP desires to promote awareness and understanding of

the importance of plant pathology to a wider audience beyond its own membership. As such, a fund for the Promotion of Plant Pathology has been set up and projects within this can be part of wider endeavours when it comes to promoting the public understanding of science, with a specific focus on the function, role and activities of plant pathology.<sup>6</sup>

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**"Plant health is the key to the sustainable intensification of agriculture to feed the growing global population by 2050. Thus, recognition, advocacy and support for the promotion of plant health is of paramount importance if the international community is to guarantee plant resources for a food-secure world based on stable and sustainable ecosystems."**

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## 2020: The year to recognise and protect plant health

Finally, one interesting development highlighted in the Spring 2019 edition of the Newsletter of the British Society for Plant Pathology is the significant announcement by the UN General Assembly that 2020 will be the year to protect and recognise plant health. IYPH 2020 is the International Year of Plant Health and the IPPC – International Plant Protection Convention is: "An international treaty that aims to secure coordinated, effective action to prevent and to control the introduction and spread of pests of plants and plant products."

We know that IYPH 2020 is building up a number of resources to motivate, support and guide efforts towards celebrating IYPH 2020. According to the IPPC, healthy plants are the foundation for all life on earth, making up over 80% of the food we eat and the oxygen we breathe. They continue this interesting point with their thoughts on the importance of plant health below.<sup>7</sup>



“Plant health is the key to the sustainable intensification of agriculture to feed the growing global population by 2050. Thus, recognition, advocacy and support for the promotion of plant health is of paramount importance if the international community is to guarantee plant resources for a food-secure world based on stable and sustainable ecosystems. With this in mind, in July 2017 the FAO Conference approved a draft resolution requesting the General Assembly of the United Nations to consider declaring 2020 as the International Year of Plant Health (IYPH).”<sup>8</sup>

Certainly, one of the key aims of IYPH 2020 is to raise awareness among the general public of the important role of plant diseases, which can be done, for example, through events in the UK. Looking ahead, the European and Mediterranean Plant Protection Organization is of the opinion that during 2020, the necessity to raise public awareness and the importance of international cooperation in plant health should be priorities. That ties in really well with the aims of the British Society for Plant Pathology, some of which have been explored in this article. ■

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# Plant pathology: The global impact of wheat diseases

Dr Kim Hammond-Kosack at Rothamsted Research highlights an aspect of plant pathology that concerns the importance of finding new ways to disarm old enemies in wheat diseases

Wheat is the number one arable crop grown in the UK and Europe, and globally, the wheat crop provides 20% of the total calories consumed by humans each day. Wheat is also a valuable source of animal feed and is increasingly used in a wide range of manufacturing processes. The EU harvested 142.6 million tonnes of wheat in 2017.

Currently, wheat yields are not resilient to adverse weather conditions or various biotic and abiotic stresses.

As a result, 'on farm' yields remain static. Each season because of diseases caused by microscopic pathogens, predominantly specialist infectious fungal, bacterial and virus species, potential wheat yields are reduced by 16 to 25%. Pathogens rapidly grow and reproduce within wheat plants and spread disease to neighbouring fields and regions thereby causing disease epidemics and pandemics if left unchecked. Collectively, these pathogens reduce crop canopy, root system and flower health thereby lowering grain yield, quality and sometime grain safety.

Within the wheat pathogenomics research team at Rothamsted we focus on several pathogenic fungi of global importance. In this article we will feature two persistent disease problems of fungal origin which are causing the agrochemical industry, plant breeders, agronomists and

farmers frequent headaches. The first leaf blotch disease is caused by *Zymoseptoria tritici* and the second Head blight disease is caused by a group of *Fusarium* species (Figure 1).

Our multi-disciplinary team includes plant pathologists, molecular biologists, geneticists, computational biologists and field crop scientists. We are pursuing a two-pronged experimental approach. On the one hand we investigate how fungi attack wheat and cause disease by discovering the genes, proteins and chemical metabolites involved, as well as defining the underlying interconnecting networks which co-ordinate the early infection process.

In concert with this, we are exploring the molecular processes used by wheat cells to perceive fungal pathogen attacks as well as dissecting the plant defence components that are activated to rapidly stop fungal growth and minimise disease formation. In recent years, our discovery research toolbox has been substantially improved thanks to the full sequences of pathogen and wheat genomes becoming available (i.e. their DNA blueprints).

## Finding pathogen genes required for stealth or attack

To be successful, a pathogen needs initially to attach itself to, and then grow along, across and ultimately into, plant tissues. Whilst doing so it must also mask its presence and remain

symptomless, until its size and strength becomes sufficient to overwhelm the plant and cause disease. Our group has identified several key genes from both *Fusarium* and *Zymoseptoria* species which are important for these events. By randomly inducing mutations into the genome of *Zymoseptoria* and then testing for mutants which could not grow on leaf surfaces, we've identified a key virulence gene *GT2* (a specialist enzyme called glycosyltransferase 2). The identical *Fusarium* gene is also crucial for the infection of wheat floral tissues. Inactivation of these genes would likely protect plants from the corresponding diseases. We've also identified a key "stealth" gene called *3LysM* which prevents *Zymoseptoria* being recognised early on by the plant's defences, thus giving it time to build up inside the infected wheat leaves. Blocking this fungal gene would also likely prevent disease.

## Finding wheat genes required to stop pathogens

To be successful, a plant needs to recognise an invading pathogen and rapidly switch on an effective defence response as well as prepare for subsequent attacks.

Despite *Zymoseptoria* being such an important wheat pathogen, only a small number of genes for resistance to *Zymoseptoria* have been identified so far and surprisingly very little is known about how these genes actually operate to protect wheat.



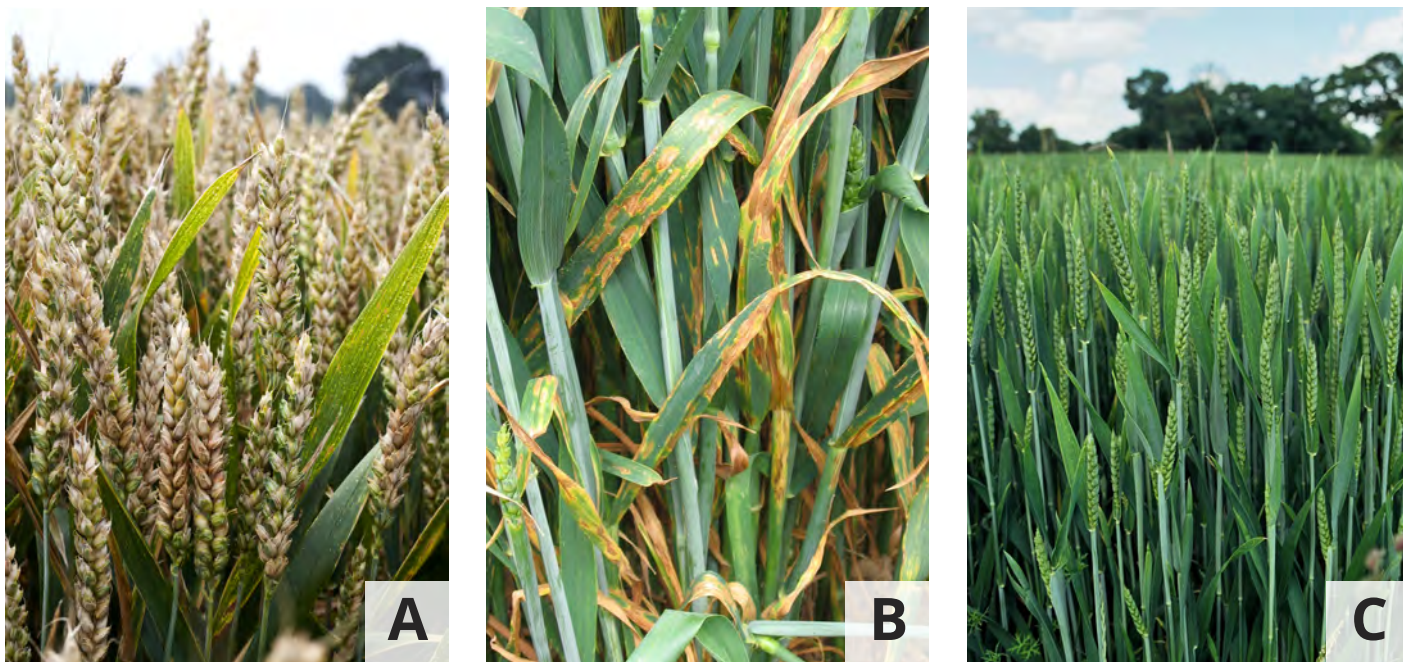


Figure 1 (A) *Fusarium* Head Blight. *Fusarium* species infect the flowering crop causing premature bleaching of floral tissues. Infection results in lower quality grains contaminated with hazardous mycotoxins that are regulated by the European Food Safety Authority. (B) *Septoria* Leaf blotch. *Zymoseptoria tritici* causes the complete death of infected wheat leaves, preventing the plant from capturing sunlight needed for plant growth. Both fungal species are either partially to fully resistant to all commercial fungicides. (C) A healthy wheat crop.

To help us answer some of these questions, we isolated the very first *Zymoseptoria* resistance gene from wheat known as Stb6. This gene belongs to a large previously uncharacterised gene family in wheat, codes for a cell wall residing immune receptor protein that senses a protein secreted by *Zymoseptoria* during attempted infection and triggers defence.

Unravelling the molecular mechanism of Stb6 mediated resistance will help inform future effective strategies for disease control. Moreover, the knowledge already gained in our studies will help to isolate additional resistance genes for deployment through breeding in wheat improvement programmes.

## Outlook

The most sustainable solution to reduce plant diseases is through delivering life-long protection within or on the planted seed. This can be achieved by combining a triad of approaches. Through plant breeding

by 'stacking' or 'pyramiding' multiple disease resistance genes that activate different plant defences against the same pathogenic species.

By removing or inactivating disease susceptibility genes that were unwittingly incorporated into elite cultivars by breeders when introducing another, beneficial trait. Through the application of novel chemicals or biological agents to the seed in coatings that go on to combat infections throughout the life-span of each plant by reducing the effectiveness of pathogen stealth or attack genes.

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**Dr Kim Hammond-Kosack**  
**Research Programme Leader Wheat Pathogenomics**  
 Rothamsted Research  
 Tel: +44(0) 158 293 8240  
[kim.hammond-kosack@rothamsted.ac.uk](mailto:kim.hammond-kosack@rothamsted.ac.uk)  
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# Building innovation ecosystems to support the energy transition

Dr Christoph Frei, Secretary General of the World Energy Council shares his thoughts on building innovation ecosystems to support the energy transition

In my recent conversations with ministers, I am repeatedly asked the same question: 'How can I, as a ministry and a country, support the Innovation Ecosystem?'

What does an Innovation Ecosystem mean? It means access to and availability of relevant skill sets, synergetic business networks, financing support schemes from venture capital to equity partners, as well as regulatory support and sandboxing where needed. For a ministry, it is ultimately about understanding the policy requirements that come out of the innovation space, as well as having the infrastructure readiness to respond to new solutions.

The dramatic increase in extreme weather events and the continued increase in human-made carbon emissions speak a clear language: we are falling behind on climate objectives and impact opportunities and must accelerate the energy transition today. A transition that delivers against the objectives outlined by the Energy Trilemma.

The World Energy Council has said it very clearly: to accelerate, we need both ambitious policies and new technologies delivered through innovative business models.

Supporting innovators is a priority for the World Energy Council and fundamental to accelerating the energy transition. The Council has partnered with dena, the Germany Energy Agency to bring 100 Innovation finalists from our Start-up Energy Transition Awards programme to the 24th World Energy Congress in Abu Dhabi next September. The SET platform is part of the Council's Impact Communities, helping to build capabilities and better manage the challenges of the energy transition.



*Dr Christoph Frei  
Secretary General*

However, start-ups alone are not enough to deliver the acceleration we need. We need to upgrade policies to take advantage of sector adjacencies – first, adjacencies between power, heat and gas and then digital, transport and finance looking at sector coupling and harvesting unrealised infrastructure benefits beyond single sectors and narrow supply chains. That also means upgrading policy to include circular economy thinking. Consider the battery: how important have batteries become? What happens to a battery if it's not recycled? How big is the opportunity for recycling waste in terms of energy? How can the digital enabling of existing assets deliver storage and system flexibility rather than building costly new assets? Questions like these are critically important if we want to achieve cost-effective transition pathways.

There is still a deep misunderstanding of the extent and importance that the Energy Transition will play in a country's ability to be competitive. Considering that half the world's capital is invested in energy and its related infrastructure, the capability of handling the Energy Transition has grown into a backbone of industrial strategy and overall economic prosperity, with implications far beyond the energy sector. It also





means that the Energy Transition is not just an Energy Minister's concern, but a key matter on Prime Ministers and G20 agendas.

On a global scale, achieving a successful Energy Transition requires the trade to deploy the sharing of best technologies and thereby accelerate learning curves, implementing a CO2 price and mitigating against regional tensions arising from shifting resource utilisation. What happens to regional balances when they come under pressure and haven't diversified fast enough? Countries that transition too quickly are likely to see a social backlash, because of price spikes and skills mismatch.

There is no guarantee that an entirely unguided transition leads towards a better world. Decarbonisation takes a carbon signal. Accelerating learning curves takes technology trade. Diversifying energy systems takes lead time and effort, especially in regions exposed to pressure.

Traditionally, energy followed a Maslow pyramid pattern for development. It was about access first; making it cheaper before making it more secure and clean. This

approach is now problematic and can sometimes end up with much more expensive solutions, including much higher costs for infrastructure and beyond. Instead, we need a more strategic approach, balancing social, environmental and security objectives – always. Careful planning and transition management are paramount in delivering a low-cost and socially viable transition.

The beauty is that today we have the technologies and opportunities to help achieve a successful energy transition, but we still need innovative policy frameworks and market designs and closer collaboration across sectors and competencies to help close the current investment gap and to ensure that an affordable and just energy transition is delivered for the benefit of all. ■

**Dr Christoph Frei**  
**Secretary General**

World Energy Council  
Tel: +44 (0)207 734 5996  
[www.worldenergy.org](http://www.worldenergy.org)



# The energy future of developing countries: Technological “leapfrogging” to deal with global warming

José Goldemberg, Professor Emeritus at the University of São Paulo, Brazil Institute of Energy and Environment, explains all we need to know about technological “leapfrogging”, a strategy to face the problem of global warming and the energy future of developing countries

2018 was the fourth hottest year on record; last year, global land and ocean surface temperatures were 0.79 degree Celsius above the 20th century average. Since 1880 when record keeping had only been around for three years, 2015, 2016, 2017 were hotter. Much of Europe, the Mediterranean, New Zealand, Russia and parts of the Atlantic and the Pacific Ocean faced heat waves. The most impacted area was the Arctic, which is warming faster than the global average.

Scientifically, there is little doubt that the main driving force behind global warming is the increased consumption of fossil fuels (coal, gas and oil) from which over 80% of all energy used in the world originates. The use of fossil fuels leads inexorably to the emissions of carbon dioxide (CO<sub>2</sub>) which is the main gas responsible for global warming. There are others such as methane and chlorofluorocarbons (CFCs), which contribute less.

The developed countries in Europe, the United States and Japan, which benefited first from the industrial revolution of the 18th century, were the main emitters of CO<sub>2</sub> until the end of the 20th century. These countries are usually labelled as the OECD

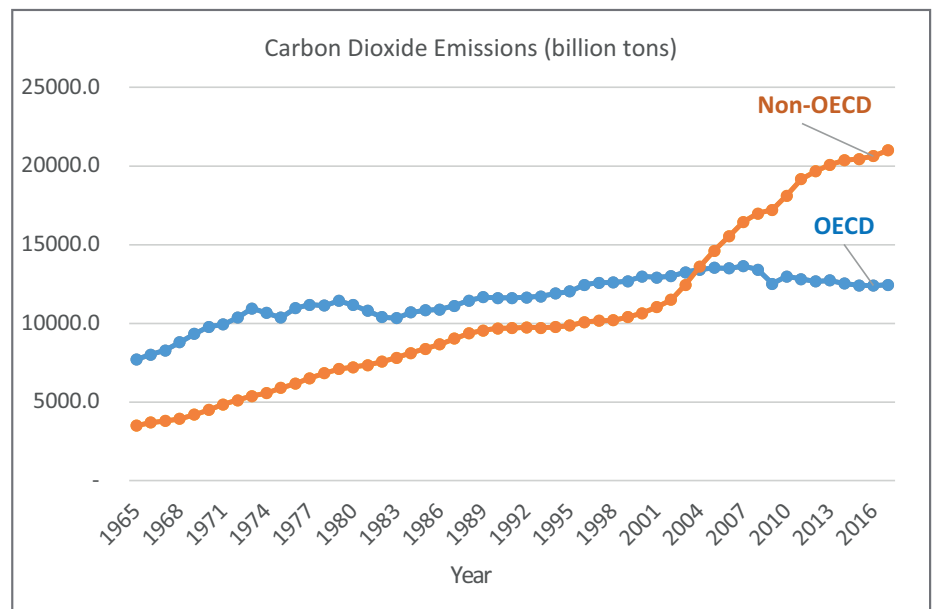
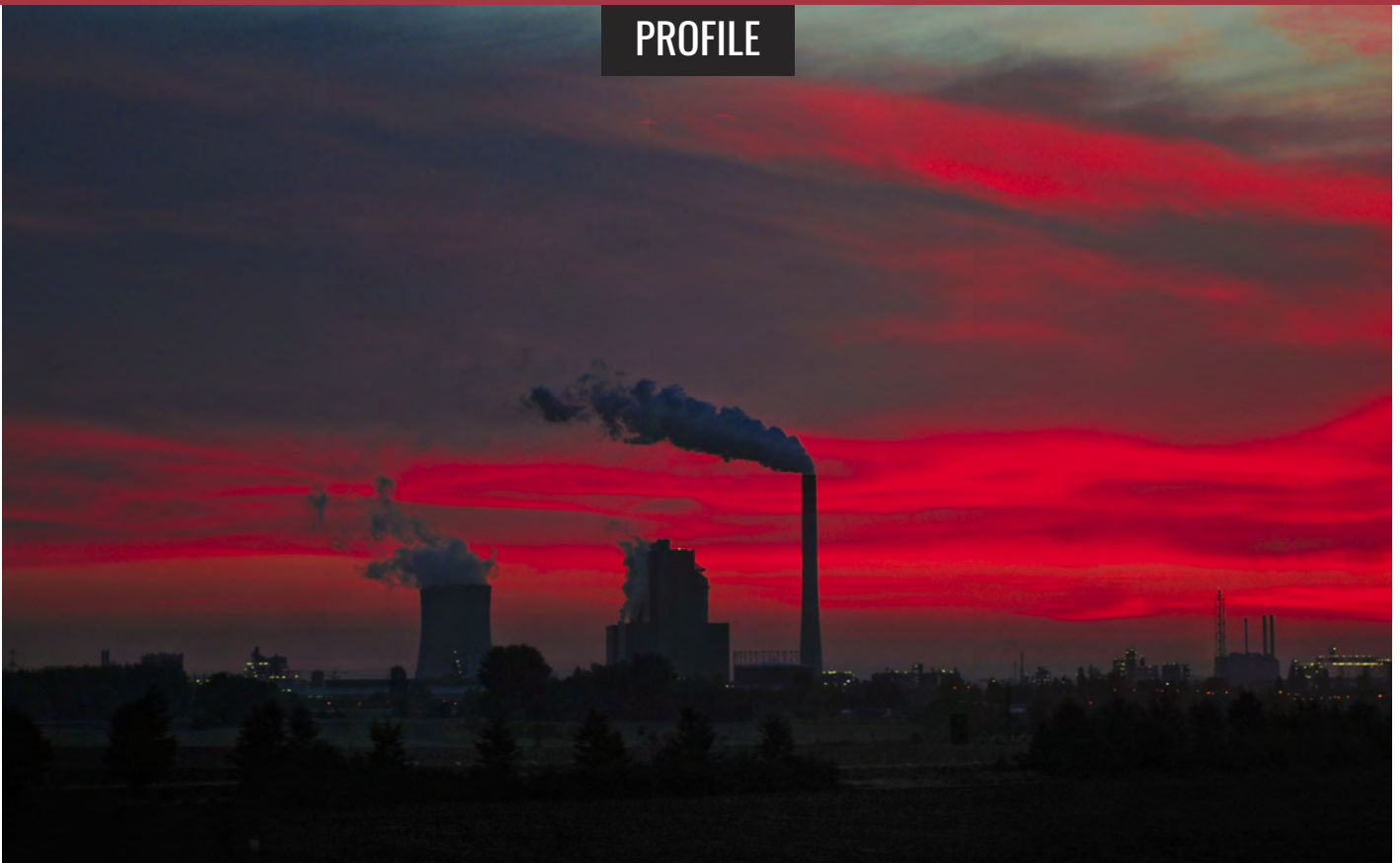


Figure 1

(Organization for Economic Cooperation and Development) countries and have a population of approximately 1.2 billion people. In all the others (non-OECD countries), the population is approximately 6 billion people. This group of countries includes all the former colonies and the less developed regions of the world, which are latecomers in the development process and use the technologies developed in the industrialised countries. However, as the population of the non-OECD countries increased and they started to industrialise their emissions grew explosively as shown in Figure 1.

The growth of emissions in non-OECD countries, due mainly to the rapid industrialisation of China – in contrast to the fact that emissions of OECD countries have flattened out – is a serious cause of concern for the sustainability of the world climate system. At the end of the 20th century, CO<sub>2</sub> emissions of the OECD and non-OECD countries were approximately the same but since the population of the OECD countries is much smaller their “per capita”, emissions were much higher.

To face these problems, one has to try to understand what the drivers of the



flattening of the growth of CO<sub>2</sub> in the OECD countries are. The most important of them is the increase in the efficiency of the production of energy from fossil fuels: Watt's original machine – which converted heat (from the burning of coal) in mechanical work (and later on in electricity) – had an efficiency of approximately 3%. Present thermal plants generating electricity have efficiencies in place at least 10 times higher. In other words, much more energy is produced using less fuel. The efficiency in using this energy has also increased considerably.

The increase in the efficiency of energy production from fossil fuels is due in great part to the competition between companies of the industrialised countries which spurs technological innovation. Successful companies with a monopoly on some technology are bound to take fewer risks; they stand to lose their technological leadership role when competitors, willing to take more risks to adopt new technologies. Such are the

“gales of constructive destruction” described by Schumpeter <sup>(1)</sup>.

In addition to that, the increased use of renewable energy sources (which do not emit CO<sub>2</sub>) such as hydropower, wind machines, photovoltaics and biomass, contributed to the reduction of carbon emissions.

Another driver that helped innovation was the need to reduce the local pollution originating mainly from the use of coal and oil. These fuels have impurities that thrown in the atmosphere, are the cause of fog, acid rain and other environmental problems which are not tolerated by the population (mainly in the larger cities) and led to the introduction of strict environmental regulations. The compliance of such regulations stimulated further technical advances.

The problem we face now is how to encourage developing countries to adopt these technologies – or eventually new ones – to reduce the fast growth of their CO<sub>2</sub> emissions.

Part of the response consists of transferring current technologies in OECD countries into developing countries. This was done routinely in the colonies of the imperial powers of the 19th with second rate and sometimes obsolete technologies.

However, developing countries can avoid retracing the development process previously followed by industrialised countries in the past. In other words, developing countries have a choice; they can either mimic industrialised nations and undergo an economic development phase that is dirty, wasteful and creates an enormous legacy of environmental pollution or they can “leapfrog” over some of the steps of development and incorporate currently available modern and efficient technologies into their development process <sup>(2)</sup>.

An example is solving the lighting problem in many isolated villages where kerosene lamps and candles are used. Bringing electricity to these villages and replacing kerosene and

candles by incandescent light bulbs is the usual solution adopted in many countries. A much better solution is to generate electricity locally in PV (photovoltaics) panels and powering compact fluorescent lightbulbs (CFL). A PV-CFL system is some 100 times as efficient as kerosene and a half-million times more efficient than candles. The PV-CFL solution leapfrogs over its alternative: a large expensive electric generating station sending power over many miles of transmission and distribution lines, supplying a bulb that ultimately converts less than 1% of the original fuel energy to light <sup>(2)</sup>.

What experience shows is that many of the improvements in industrialised countries have made their way into less developed countries. Examples are given by the automobile industry where some cars manufactured in India and China have fuel economics better than models used in the U.S. In steel production, in general, developing countries produce more steel per tonne using less energy than many European countries. New refrigerators in China today consumes much less energy than in the United States 30 years ago i.e. China has "leapfrogged" stages in this area <sup>(3)</sup>.

Another outstanding example of such "technological leapfrogging" is the Ethanol Program in Brazil. The Program started in 1975 when, in response to an international oil crisis, the government launched the National Alcohol Program (NAP) with the aim of alleviating some of the country's dependence on fossil fuels. Back then, there was great interest in how crops, already in production in large scale such as sugarcane Brazil, could be used to produce ethanol and other ethyl-alcohol fuels.

In a 1978 paper, published in *Science*, we looked specifically at the energy cost and expenditure of several different crops: sugarcane, cassava and sweet sorghum. These specific crops are essentially a form of non-polluting solar energy: the rays of the sun provide the crops with the energy they need to grow – and a little extra; that extra energy is stored by the plants – quite literally saved away for a rainy day – and can be extracted in the form of ethyl-alcohol at a later date <sup>(4)</sup>.

Such work demonstrated that sugarcane was the most efficient crop to use when converting this solar energy into a chemical fuel and it paved the way for the Brazilian energy-boom that followed. Today, an estimated 50% of the gasoline that would be in use for fuelling cars in Brazil has been replaced with ethanol from sugarcane, a renewable fuel <sup>(5), (6)</sup>.

There are more than 100 hundred countries in the world producing sugar from sugarcane and the successful ethanol program in Brazil could be replicated in other countries as an alternative to electric vehicles.

The United States developed a similar programme producing large quantities of ethanol from corn which started in the year 2000 following the steps of the pioneering Brazilian program.

There are many other examples of "technological leapfrogging" going on in developing countries which were identified by local scientists that are more adapted to the national resources and peculiarities of their countries.

"Technological leapfrogging" provides a route for scientists in developing

countries to skip over the potential stumbling blocks of using unsuitable technologies and in Brazil, it has been used to alleviate one of the biggest problems we face today: the global energy crisis and global warming. Expanding the approach globally could shape the energy-climate for future generations around the globe.

The energy future of developing countries is not a matter of destiny but choice.

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**José Goldemberg**  
**Professor Emeritus**  
 The University of São Paulo, Brazil Institute  
 of Energy and Environment  
 Tel: +55 11 3091 5053  
 goldemb@iee.usp.br



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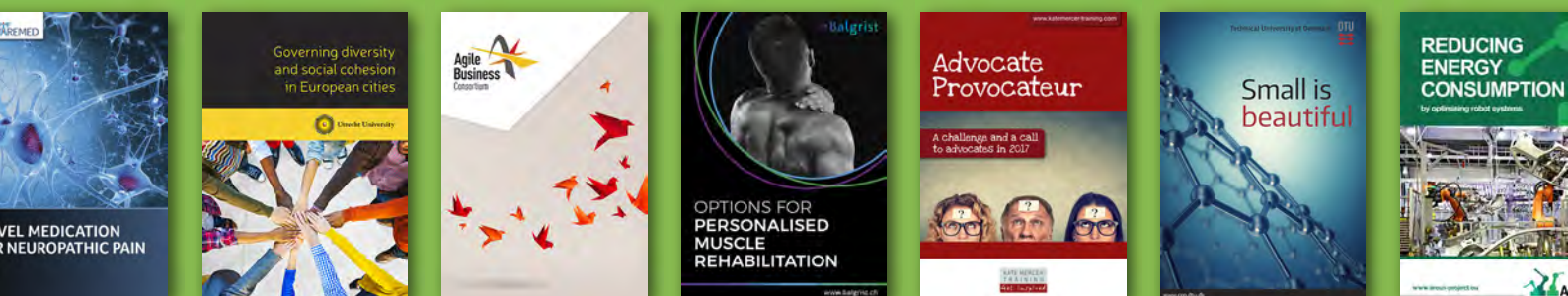
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# Hydrogen helping the environment, reducing carbon emissions

**Morry Markowitz, President of the Fuel Cell and Hydrogen Energy Association details how policies have been implemented that increase the role of hydrogen in various applications – including transportation as one method reducing carbon emissions**

Over the past several years, countries, states and other jurisdictions around the world have implemented policies increasing the role of hydrogen in various applications – transportation, stationary power and energy storage – as one method reducing carbon emissions in these sectors.

However, with the number of hydrogen-powered fuel cell systems already in operation on the road in vehicles and deployed on the ground in stationary systems steadily climbing, with more to come on the horizon, many are asking, “is hydrogen really clean?” The plain and simple answer is yes!

In the transportation sector, there are a lot of misconceptions about hydrogen and its use as a fuel. To understand why governments, industry and consumers are increasingly working to utilise this energy powerhouse to meet environmental goals, we must start with the basics. Fuel cell vehicles, or FCVs, are electric vehicles. However, rather than getting power from the grid to recharge, an FCV generates electricity onboard the vehicle, combining oxygen from the air with stored hydrogen fuel, with the only tailpipe emission being water vapour. FCVs are the only zero-emission vehicle platform now and for the foreseeable future, that replicates today's drivers' experience of being able to travel 300-400 miles on a tank of hydrogen fuel and then refuel in just three to five minutes.

Hydrogen is the lightest and most abundant element in the universe, however, as hydrogen is not naturally occurring, it can only be obtained from other sources. The most common methods of hydrogen production are either reforming of conventional hydrocarbons, typically natural gas, or through electrolysis, a process



*Morry Markowitz*

where an electric current is run through water to produce a stream of hydrogen and oxygen.

When using renewable electricity from solar or wind to power electrolysis or renewable biomethane from landfills or wastewater treatment plants, hydrogen production is completely decarbonised. Just as battery electric vehicles are getting cleaner as the utility grid adopts more renewable power generation, so too is hydrogen production driving its emissions lower.

As some critics have pointed out, certain methods of generating hydrogen do produce some greenhouse gas. However, as the overall goal is to reduce harmful emissions in the transportation sector, many studies, including those by the U.S. Department of Energy's Argonne National Laboratory, have demonstrated that no matter the source of hydrogen, FCVs still dramatically reduce carbon emissions compared to gasoline vehicles. In fact, FCVs are comparable in emissions to battery electric vehicles (BEVs) that use grid electricity.



faster path to zero-carbon intensity than the one charted by utilities for the grid.

If the policy aim is to transition to a zero-emission transportation sector, BEVs will not be able to do it alone. Utilising quick-fill centralised fueling stations and the long driving range that consumers are used to, not to mention scalability to all vehicle platforms, FCVs offer a ready choice that fills a need, especially for consumers in multi-family housing, city dwellers, or in locations with limited parking options where charging is not available. While BEVs may be a great choice for some consumers, if we want to have the greatest adoption of zero-emission vehicles, we need to expand the portfolio to include FCVs, too. We are doing that now and the pace of change is only growing.

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**“In the transportation sector, there are a lot of misconceptions about hydrogen and its use as a fuel. To understand why governments, industry and consumers are increasingly working to utilise this energy powerhouse to meet environmental goals, we must start with the basics.”**

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Another common misunderstanding is the claim that the process of producing hydrogen from natural gas uses more energy than what would be left in the hydrogen generated – meaning it would be more economical to use the natural gas directly as a fuel for an internal combustion engine car. While some energy is lost in reforming natural gas into hydrogen, this argument discounts the extremely inefficient process of combustion engines and does not consider the much higher efficiencies of fuel cell electrochemistry. An FCV using hydrogen derived from natural gas would allow a vehicle to travel two to three times further than a compressed natural gas vehicle using the same amount of fuel. FCVs offer a much more efficient and environmentally friendly means of using domestically-produced resources.

The ultimate goal is to completely decarbonise our transportation system. That is why at the Global Climate Action Summit in San Francisco last fall, several of the largest companies in the fuel cell and hydrogen industry announced an ambitious goal to fully decarbonise hydrogen as a transportation fuel by 2030. This goal would set the stage for a significant environmental impact and put hydrogen-fuelled transport on a much

Beyond transportation, thousands of hydrogen fuel cells are also being used today to provide zero-emission stationary power generation for a long list of private and public sector customers across the country and around the world. These fuel cell systems are generating clean, efficient, long-lasting and reliable back-up power for communications networks, utilities, governments, railroad and traffic signals and even microgrids.

On-road and off, hydrogen is a clean energy solution that is helping transition to a better future today. ■

**Morry Markowitz**  
**President**

Fuel Cell and Hydrogen Energy Association

Tel: +1 202 261 1331

[info@fchea.org](mailto:info@fchea.org)

[www.fchea.org](http://www.fchea.org)

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# Power to gas: The steps from theory to practice

The European research project STORE&GO at the finish line and about to publish a roadmap for the future integration of power-to-gas technology, writes Dr Frank Graf from the DVGW Research Centre at the Engler-Bunte-Institute of Karlsruhe Institute of Technology

The STORE&GO project is in the last months of its four-year duration. Three power-to-gas demo sites are in operation and produce first well-founded results. Cross-cutting activities deal with various technical and techno-economic analyses and regulatory recommendations for Europe. Results will be published over the coming months, culminating in a European power-to-gas roadmap. This will provide a strategy on how to integrate this promising technology into the continent's energy system and how to contribute to the energy transition.

## STORE&GO demo sites are in operation – another step towards a successful and renewable energy transition in Europe

The growing number of renewable power sources will demand long-term and large-scale storage in the future. One option is power-to-gas (PtG) that allows for storing power by producing synthetic hydrogen or methane. Generating gas from renewable electrical power with PtG is by far the most promising way to store large amounts of energy. It also reduces the need and cost of expanding the electricity grid.

To develop the technology further, three demonstration sites have been installed within the STORE&GO project. The first to operate was the power-to-gas plant in Falkenhagen, Germany. Its



Figure 1: STORE&GO power-to-gas plant Solothurn, Switzerland

existing power-to-hydrogen process was expanded by a methanation stage in May 2018 and synthetic methane has been fed into the natural gas grid since January 2019. This allows the partners of the international research project STORE&GO to demonstrate the technical feasibility of the power-to-gas process for feeding “green” gas into the natural gas grid.

At present, the plant produces up to 1,400 cubic meters of synthetic methane (SNG) per day, which corresponds to approximately 14,500 kWh of energy. For comparison purposes, with this amount of energy, 200 golf class CNG cars could drive about 150 km per day. The plant has already achieved over 700 operational hours with a methane purity reliably above 99%. The green methane is produced

from hydrogen which, in turn, is generated with electricity from renewable sources and CO<sub>2</sub> from a bioethanol plant. The heat generated during the process is used by the nearby veneer mill, which increases the overall efficiency of the plant.

The second STORE&GO demonstration site is located in Solothurn, Switzerland (see Figure 1). It is the only one of the three STORE&GO plants that use biological methanation. Countless microorganisms, so-called Archaea, convert hydrogen and CO<sub>2</sub> to methane in the central vessel. After many busy months working with high intensity to finish the plant, the operators could finally animate the frugal microorganisms to spawn and to generate methane. The Solothurn plant has been producing methane since May 2019.



## Power-to-Gas roadmap

The STORE&GO project partners are working on channelling the results into a European PtG roadmap. The power-to-gas roadmap is being prepared and will be finished by the end of the project. All generated results and scenarios will be combined to set up a strategy for the integration of power-to-gas technology in Europe. The roadmap aims at a holistic approach considering a wide range of aspects such as techno-economic feasibility of energy storage operations, integration of PtG concepts in the electricity grid management and power supply, reduction of regulatory barriers for PtG, as well as potential market uptake for PtG across Europe.

On 3rd December 2019, STORE&GO will host a political dinner at the European Parliament, presenting the STORE&GO roadmap and other project results, with key stakeholders from politics, industry and the scientific community. The goal is to discuss all emerging topics regarding PtG and to showcase potential scenarios to implement PtG in Europe for the European energy transition.

The community of Troia in Italy houses the third of the STORE&GO demo sites. This plant combines direct CO<sub>2</sub> capture from the air and a novel milli-structured methanation unit with an innovative micro-scale liquefaction unit for the produced methane. Such a sequence of new technologies displays possibly the most experimental one among the STORE&GO plants. The Troia process chain produced methane for the first time in April 2019. All three plants will use the remaining project duration to gather experience from the operation and to provide real data for further analysis within the project.

## Analyses show: Power-to-gas increases energy security and lowers total costs of the energy system

The STORE&GO partners also performed a full cost-benefit analysis to assess the macro-economic value of having PtG in the year 2050. Results show that PtG lowers the total costs of the energy system and that it prevents more expensive investments or higher operational costs in other parts of the energy system. PtG increases the energy security of the energy system

by lowering the probability of shortages of energy, for example, during periods of low wind and solar energy production in Europe. PtG could ease bottlenecks in the electricity grids and allow for including renewable energy at lower costs than what would be required for extending electricity grids.

From a technological point of view, renewable gases are ready to be integrated within the energy system. However, the current legal and regulatory framework and market conditions impede the installation of industrial-scale power-to-gas plants and the ramp-up of gas production. STORE&GO partners found out that an optimised plant layout combined with proper market conditions would enhance the viability and offer opportunities in particular for seasonal storage of renewable energy. For the future legislation period in Europe, it will be necessary to find a legal category for PtG, to define who is allowed to operate it and to harmonise rules for operating gas networks. The consortium will shortly publish all results mentioned herein deliverable documents on the project website and in peer-reviewed scientific publications.



### Dr Frank Graf

DVGW Research Centre at  
Engler-Bunte-Institute of  
Karlsruhe Institute of Technology (KIT)  
Tel: +49 721 608 412 21  
graf@dvgw-ebi.de  
<https://dvgw-ebi.de/>

# Green hydrogen: Produced from renewable energy sources

Vegard Frihammer, Green Executive Officer/Founder of Greenstat provides a fascinating look at green hydrogen, which is produced from renewable energy sources

**G**reen hydrogen is defined as hydrogen produced from renewable energy sources. Around 97% of Norwegian electricity production comes from hydropower and with 15 TWh of excess capacity currently available, new ways of utilising this green power are needed. In the form of hydrogen, surplus and trapped renewable energy can be stored, distributed and made accessible to growing zero emission markets, both in Norway and abroad, placing our country in a unique position when it comes to green hydrogen production.

## Both large scale and small-scale hydrogen production plants needed

When setting up a hydrogen production plant, the question of whether to place the facility close to the consumer or close to the power production is raised. As the sale price of hydrogen will be a result of the production and the transportation costs this will vary depending on the location of the consumer and of the power source. The production price is significantly reduced by setting up large scale production facilities, but to keep the transportation costs down you need large consumers nearby.

## Electrolysis as the end solution, but fossil hydrogen with CCS could speed up the transition

Norway has a large production of natural gas with a yearly export of nearly



1000 TWh. For the Norwegian gas industry, hydrogen could provide a new market and even if green energy from renewable energy is the favourable solution in a climate perspective, hydrogen with CCS (carbon capture storage) could boost the transition by securing stable large-scale production from existing facilities.

However, hydrogen from natural gas with CCS is only economically viable in large scale, several hundred tonnes per day and close to existing CCS infrastructure, leaving room for green hydrogen to cover most of the domestic market in Norway where smaller projects in the range of a few hundred kilos per day to some tonnes per day will be the typical project size.

## Hydrogen is an important piece of the zero-emission puzzle

Hydrogen has some fantastic characteristics as a zero-emission energy

carrier. It has very high energy to weight density and only emits water. It can be produced anywhere from renewable energy and works very well as a range extender in existing electrical drive lines. However, hydrogen must not be seen as the only solution. Hydrogen will, in combination with batteries and a share of sustainable biofuel, play a key role in the transition to a 100% zero emission transport.

## Green distribution of green hydrogen

Hydrogen can be distributed compressed, liquefied or through a pipeline. Both on land and by sea, hydrogen could be distributed in compressed or in liquefied form. By fueling the distribution trucks and ships with hydrogen, the value chain is green all the way from production to consumer.

## Liquid hydrogen

Hydrogen has a higher specific energy per unit than fossil-fuels, but a lower





energy density per unit. In short, it takes up less weight but more space than the current solutions. There are two solutions to this problem; compression and liquefaction, the second of which offers the best density at the expense of costs and complexity. Therefore, there are use cases for both compressed and liquefied hydrogen depending on energy demands and space availability. For example, a supply vessel to the oil and gas industry would need about six tonnes of hydrogen for a standard three-day operation. In gaseous form, hydrogen at 350 bar pressure would need storage of about 250 m<sup>3</sup>, compared to only 85 m<sup>3</sup> in liquid form.

Liquid hydrogen has been chosen for the first ferry project in Norway, with the hope of creating a bridge to more vessels. Supply vessels, cruise ships and for that matter large bulk ships, travel far greater distances than an express boat or car ferry and will need much more fuel.

Still, an important area of development is larger storage tanks, suited

for long distances. On the flip side, fuel cells have a higher efficiency than combustion engines, reducing the amount of energy needed. Often compared to the far greater energy efficiency of battery electric systems. It is important not to pit the two solutions against each other because they serve different purposes.

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**“Hydrogen has some fantastic characteristics as a zero-emission energy carrier. It has very high energy to weight density and only emits water. It can be produced anywhere from renewable energy and works very well as a range extender in existing electrical drive lines.”**

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## Summary

Lately, major gas producers have made public plans to increase the global production capacity of liquid hydrogen from 300 to 400 tonnes per day. However, a key question remains, the use of emission-free hydrogen. If hydrogen is to be a zero emission solution, then hydrogen production from renewable electricity must increase and facilities producing it via natural

gas reforming must implement carbon capture and storage.

The challenge ahead is, therefore, to increase the tempo even faster, encourage the production of truly zero emission hydrogen and take advantage of economies of scale. The climate puzzle is far from done, but with hydrogen, we are holding a key piece that can Make Green Happen!

## GREENSTAT

**Vegard Frihammer**  
**Green Executive Officer/Founder**  
 Greenstat  
 Tel: +47 9282 6952 (Norway)  
[vegard@greenstat.no](mailto:vegard@greenstat.no)  
[www.greenstat.com](http://www.greenstat.com)  
[www.twitter.com/frihammer](https://www.twitter.com/frihammer)

# Bridging the gap to a decentralised energy future

Aggreko's Managing Director of Northern Europe, Chris Rason, provides his thoughts on bridging the gap when it comes to a decentralised energy future in the UK

UK industry is operating in a highly competitive world in which the price of energy can have an enormous impact on our ability to be competitive on the global stage. However, attempts to reduce energy consumption can run into familiar road-blocks, such as the UK's ageing and inefficient asset base and capex constraints associated with implementing potential solutions.

Energy bills can constitute 20 to 25% of a plant's overall operational budget, often making it the largest expense for site owners and operators. Reducing costs in this area is a key concern across the industry, yet the low-hanging fruit of energy-efficiency measures, such as LED lighting, have largely been picked. As a result, there is now a need to explore new and innovative technical solutions, including decentralised energy, if UK industry is to remain competitive.

With the market for decentralised energy and storage systems continuing to grow year-on-year, it is worth evaluating the technology's benefits and its viability as a solution to these issues. A decentralised energy solution can involve harnessing solar power, combined heat and power (CHP), gas generation or wind power technology to produce energy on-site. Through the adoption of energy-efficient decentralised solutions, companies can have more control over their energy costs and usage. Because of this control, these businesses can realise cost and efficiency savings that may not be possible importing electricity from the national grid.

Consequently, an increasing number of key energy decision-makers across the industry have considered on-site energy generation, taking into account concerns about energy costs and sustainability. As such, decentralised energy technology may be ideally placed to resolve anxieties around rising energy prices impacting

the competitiveness of UK manufacturers abroad and the national grid's ability to cope with snowballing demand without stunting growth.

## Incremental adoption

Yet though larger manufacturing organisations can turn to decentralised energy as an independent source of power, it is not a viable option for all businesses. Some companies are often unable to afford the initial investment required to take advantage of the technology. Indeed, it is common for energy decision-makers to have their request for new equipment to reduce energy consumption turned down because of capex restrictions.

With this in mind, some manufacturers are now considering more incremental strategies and solutions such as demand side response (DSR) to lower their electricity bills. Many organisations who have engaged with DSR are now enjoying lower electricity tariffs due to the flexibility it allows, yet uptake remains limited in the UK. However, this enthusiasm, even on a smaller scale, definitely shows that there is interest in moving to a decentralised energy future, provided financial obstacles are overcome.

## Capex restrictions

Finding funding to finance large-scale installations will always be a concern for businesses, where the financial bottom line is a priority. While implementing a decentralised energy solution may seem attractive, many plant owners and operators often simply do not have the capital to allow this. However, by hiring the necessary plant equipment instead of opting for the traditional outright purchase option, energy decision-makers can avoid capex constraint concerns which may otherwise deter them from implementing decentralised energy technology.



Furthermore, this off-balance sheet option has no requirement for depreciation of tangible assets, meaning it can provide a bridging gap solution between industry's current overreliance on the national grid and a future where electricity is mainly generated on-site. By doing so, companies can more easily access innovative, secure and environmentally-friendly technologies that could offer immediate savings.

"Decentralised energy solutions enable more flexible demand and reduce energy consumption, allowing industrial and business users to participate more fully in the UK energy system," says Caroline Bragg, Senior Policy Manager at the Association of Decentralised Energy. "Users can increase their competitiveness, reinforce their security of supply and help towards meeting their sustainability and low carbon targets.

"The next few years hold exciting opportunities for industrial users. Power markets are opening up with flexible generation and demand side response, offering the opportunity for the industry to earn significant revenues in new markets – including reformed balancing services, the Balancing Mechanism and the new pan-EU platform called Project TERRE. We need to continue

this progress and put industrial, commercial and domestic users at the heart of the energy system."

In conclusion, the capex crunch affecting the UK manufacturing sector shows no sign of easing, while energy prices continue to rise and the national grid comes under increasing strain. These concerns are continuing to hamstring growth and manufacturers can find themselves in a position where they cannot be as competitive abroad and unable to afford the technology to change this. However, hiring could potentially provide a bridging gap solution to allow companies to take advantage of the benefits offered by decentralised energy, without significant capital outlay. ■

**Chris Rason**  
**Managing Director, Northern Europe**

Aggreko  
Tel: +44 (0) 3458 24 7 365  
[enquiries@aggreko.biz](mailto:enquiries@aggreko.biz)  
[www.aggreko.com/energygap](http://www.aggreko.com/energygap)



# Flexible and efficient use of electricity from renewable sources to answer society needs at all times and sectors

Professor Anke Hagen discusses the flexible and efficient use of electricity from renewable sources to answer society's needs at all times and sectors

It is an impressive view when sailing on the ferry between Denmark and Germany: the big wind farm close to Lolland with a capacity of almost 400 MW. It is only one location of the total installed ~5.x GW wind power in the country. Denmark sets one world record after the other when calculating the share of electricity production, which comes from wind. It was close to 50% in 2018. These numbers are a global snap shot of the transition from a fossil-based energy supply to the future energy system based on renewable energy sources, which many countries are currently realizing. However, the devil is in the detail. When diving into the electricity production on a time scale not of a whole year, but in daily or hourly steps, the expected finding is that there is a huge fluctuation (see the figure for a period around Christmas and New Year 2018/2019 for Denmark). With increasing the installed wind capacity, the periods, where electricity production is smaller than the consumption are becoming fewer and shorter. On the other hand, there are more frequent periods, where the consumer needs are more than satisfied. The consequences are either to trade electricity for a cheap price to neighbouring countries (see the varying spot price in the figure), to transport the produced electrons over larger and larger distances at high

costs (and significant losses), to shut down the wind turbines (when the spot price becomes negative – see yellow circle in the figure) or to develop efficient, large scale storage technologies for electricity. The last option seems by far the most economic and sustainable to utilise renewable energy sources fully.

Electricity production is only one sector, waiting for a transformation into completely fossil-free systems. In addition, the transport sector is a major challenge, contributing with ca. ¼ to the total energy balance, and the chemical industry as well. Regarding transportation, electrification is one option for vehicles, but it is certainly not delivering for all processes (what about airplanes, container ships, etc.). These challenges ask for fossil-free solutions, preferentially using renewable energy sources and closing the carbon cycle.

After considering electricity and transport, even more sectors need attention. Many of the products essential for a modern, healthy human life contain carbon in different forms, such as medical products, information technology devices, textile goods, etc. Fossil sources provide the carbon feedstock at present. Fossil-free carbon sources involve biomass, recycling or direct CO<sub>2</sub> use from industries such as cement

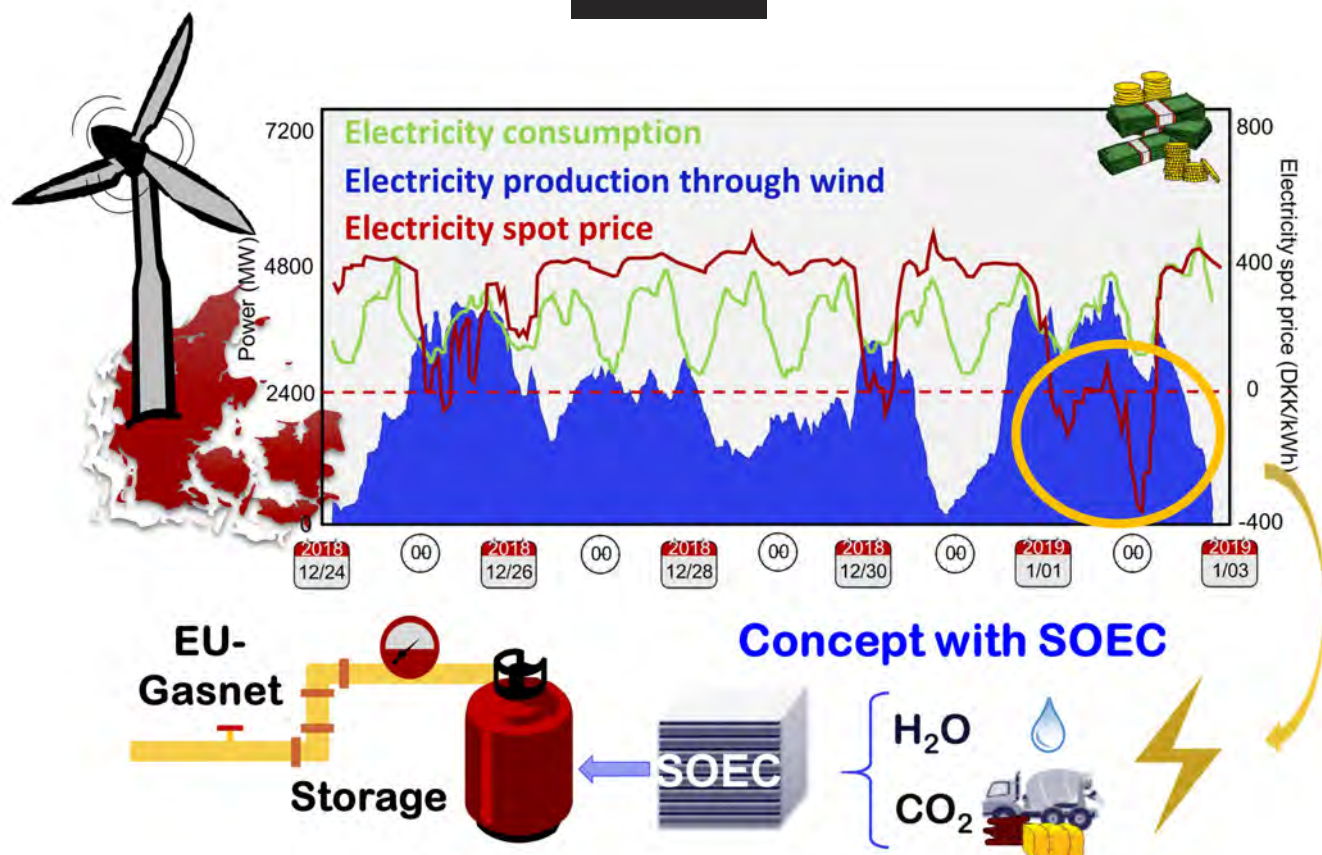
industry or recovery from air. Future technologies aim at using renewable sources for both, the electricity and carbon, which in combination yield the needed products and services.

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**“The electricity input is the major factor for the SOE system. Thus, the more “green electricity” is available in the specific grid mix, the higher is the potential for reduction of CO<sub>2</sub> emissions.”**

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What are the technologies that can provide fossil-free solutions in all sectors of modern life? Clearly, not only one single technology will be able to solve all challenges, but a smart mix of many innovative technologies. It is the ambition of our research to contribute to such a mix. One powerful option in the energy sector is electrolysis, a well-known process, which can utilise electricity from renewable sources to split water into hydrogen and oxygen. The hydrogen may be used for energy production or as feedstock for chemical products. One of the electrolysis technologies- solid oxide electrolysis (SOE) – has an additional unique feature. It can also split CO<sub>2</sub> into CO. CO in combination with hydrogen is the well-known synthesis gas, which is basis for the synthesis of many hydrocarbons through established catalytic processes (such as methanation – e-gas, methanol,



Data source: EMD International A/S, <http://www.emd.dk/el/>

ethanol, etc.). This approach is named power-to-X. Such hydrocarbons are efficient storage media for renewable energy, with existing infrastructure and logistics. They can also contribute to the transport sector or serve as feedstock for the chemical industry.

Furthermore, SOE can run in reverse mode and the same core unit, the stack, can thus produce electricity through the fuel cell mode operation (solid oxide fuel cell, SOFC). Both modes achieve extremely high efficiencies (SOE: close to 100%, SOFC: ca. 60% and higher). These features make SOE an attractive, flexible opportunity in all kind of energy scenarios. Currently, national and European funding bodies devote significant efforts to developing SOE (and SOFC).

One of the European funded projects is ECo (Efficient Co-Electrolyser for Efficient Renewable Energy Storage, grant number: 699892). This, recently completed project, combined all parts of the value chain, from CO<sub>2</sub> suppliers

(cement industry, biogas provider) via research units specialised in the core technology, the SOE and industrial SOEC technology providers, to the potential customer (gas utility). The overall objective was to utilise steam and CO<sub>2</sub> with electricity from renewable sources in an SOE, thereby producing synthesis gas, which in turn is converted to synthetic natural gas and added to the existing natural gas infrastructure for large scale and efficient storage and distribution of “green electricity”. The SOE technology was proven to operate on a dynamic electricity input corresponding to a real wind turbine profile. When the SOE operates at elevated pressure, even internal methane formation occurs, which reduces the need of the downstream catalytic unit. The electricity input is the major factor for the SOE system. The cheaper the available electricity, the higher the economic potential. The more “green electricity” is available in the specific grid mix, the higher is the potential for reduction of CO<sub>2</sub> emissions.

European players hold strong positions in R&D of the SOE technologies. The ECo project is one of a number of European and national funded projects, which all aim at maturing the SOE technology in combination with electricity from renewable sources in order to contribute to realising the transformation to fossil-free societies and to create economic benefits in Europe.



**Prof. Dr. Dr. Anke Hagen**  
**Professor**  
 DTU Energy  
 Tel: +45 46775884  
[anke@dtu.dk](mailto:anke@dtu.dk)  
[www.energy.dtu.dk/english](http://www.energy.dtu.dk/english)



# Building Regulations: Why they're no longer fit for purpose

Adrian Judd, Director of Steico, argues Building Regulations need to tighten up so that we build healthy buildings

A healthy building is one which is well-ventilated and vapour-permeable, cheap to keep both warm or cool, has high indoor air quality and maximises natural light.

Reasons to strive for a healthy building are numerous. However, current regulations focus on structural and cost-effective performance with no standards in place to regulate the 'healthiness' of the building. Without any legal requirements, people aren't aware of the many benefits of choosing healthy building materials.

## Nordic standards

To build a home that is both energy efficient and promotes good indoor air quality is well beyond the minimum building standards in the UK. This is where

Nordic countries lead the way by monitoring and measuring indoor air quality. As yet, we have no British equivalent standard.

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**"We call on the government to consider how a change in the current Building Regulations would have the beneficial effect of helping both to save energy and promote a healthier internal environment for occupants."**

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Back in 1978, a framework by the [Nordic Committee](#) included – in its standard guidelines – a regulation for indoor air quality. As part of this, all buildings (dwellings and commercial buildings alike) must have mechanical ventilation. UK guidelines on the other hand, contain no such standard.



## Why does indoor air quality matter?

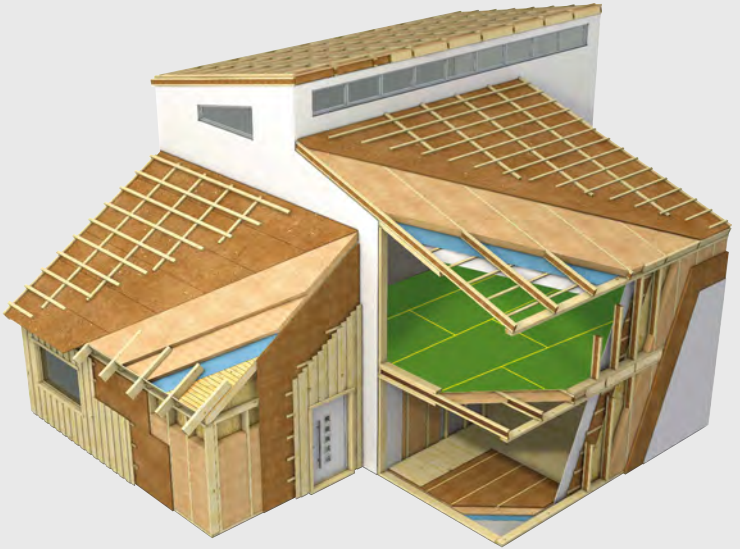
There is much evidence to support how natural building materials help to aid the standards of indoor air quality.

One reason to support this would be how wood is known for having a natural, antiseptic quality by trapping germs within its grain. The way natural materials degrade is another reason why they're healthier than synthetic materials, which emit miniscule toxic fumes over their lifetime.

Timber-based products are healthier than their synthetic alternatives because, by their nature, they allow moisture to pass through the fibre rather than keeping it out or locking it in. Their vapour-permeability dissuades the growth of mould and bacteria.

Water retention in a building's fabric can pose a serious health risk for those who suffer from respiratory illnesses.

Another natural material, lime mortar, is also known for its ability to soak up harmful gases.



## Passivhaus

Passivhaus buildings minimise the energy they use for their heating and cooling, remove as little of their surroundings as possible and aim for lower CO<sub>2</sub> emissions than the average household.

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**“Swedes and Norwegians appreciate how key indoor air quality is to humans’ wellbeing. That’s why the UK should have such a standard, as current regulations don’t cover the comprehensive performance of a building.”**

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Swedes and Norwegians appreciate how key indoor air quality is to humans’ wellbeing. That’s why the UK should have such a standard, as current regulations don’t cover the comprehensive performance of a building.

In densely populated urban areas, often opening the doors and windows does more harm than good. It invites more air pollutants to enter – eg traffic pollutants – than those it flushes out, such as cleaning fluid fumes and gases emitted from synthetic materials eg sofas, UPVC windows.

Nowadays, we’re spending more time indoors, which means there’s more opportunity for our buildings to have a determinantal effect on our health whether it’s our workplace or our home.

A house built to the current UK Building Regulations has its energy split – 53% on space heating, 28% on power and 19% heating water. A Passivhaus construction, however, splits it by 56% power, 32% hot water and 12% space heating.

Despite it being one of the UK’s lowest-energy homes, one of the first Passivhaus built in the UK, Denby Dale in West Yorkshire ([GreenBuildingStore.co.uk](http://GreenBuildingStore.co.uk)), was only awarded Level 3 cat C under EPC (Ene 1: Dwelling Emission Rate – the mandatory portion of the code’s energy category).

Such a result would suggest that the SAP methodology of the time (SAP 2005) was not accurately estimating the carbon dioxide emissions of low energy housing.



## How low can you go?

Building Regulations are a set of minimum standards. None of the 14 sections are dedicated to quality performance delivery.

For example, a new build terraced house with a tested result of  $9.1 \text{ m}^3/(\text{h} \cdot \text{m}^2)$  @50Pa passes Building Regulations. However, an external wind at an average of 20mph minutes can exchange all the heated air from within the building in just six-and-a-half minutes. This could result in an increase in heating bills of around 50%.

A resolution to this would be if Building Regulations helped to increase the quality of insulation, and therefore airtightness, with new builds to save both the money and health of the occupants.

We call on the government to consider how a change in the current Building Regulations would have the beneficial effect of helping both to save energy and promote a healthier internal environment for occupants.

In an era where the average household pays £1,163 per year for its fuel (both electricity and gas), many could halve that if their home was well-insulated with natural

materials. It would also be a healthier home. As the cost of chemicals rises, so do the prices of synthetic materials that are used in their manufacture.

In comparison, natural materials are both affordable as well as quick and easy to use.

For more information on how you can build healthy buildings, or to sign up to the healthy building campaign to show your commitment to healthy building, visit [www.steico.com/en/news/campaign/](http://www.steico.com/en/news/campaign/). ■

**Adrian Judd**  
**Director**

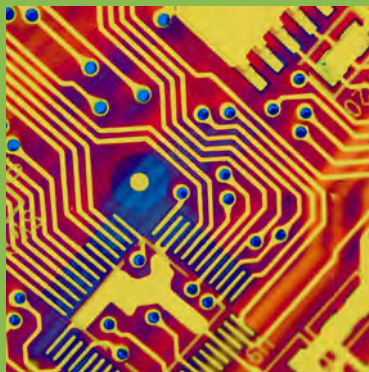
Steico

Tel: +44 (0)1727 515 120

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# Green Island: Fossil free city areas

Peder Vejsig Pedersen, Senior Advisor, MSc, European Green Cities highlights how Green Island is developing fossil free communities

**A**t the moment (during 2019), Green Island is developing a plan for a fossil-free city area with 2,000 housing units at Vinge North in the municipality of Frederikssund, situated 40 km north-west of Copenhagen in Denmark.

The vision is to obtain 100% of the energy supply from renewable energy in a cost-effective way for the inhabitants there. This will, in practice, mean use of both wind and solar energy and

solar thermal collectors in the area, therefore, supplying the main part of the energy needs.

The heat supply for the “Active House” optimised housing units will utilise low-temperature district heating, distributing heat from local heat pumps, which are connected to a local Aquifer Thermal Energy Storage (ATES) system. The ATES system utilises the groundwater as a heat source but it is based on a thermal balance from year

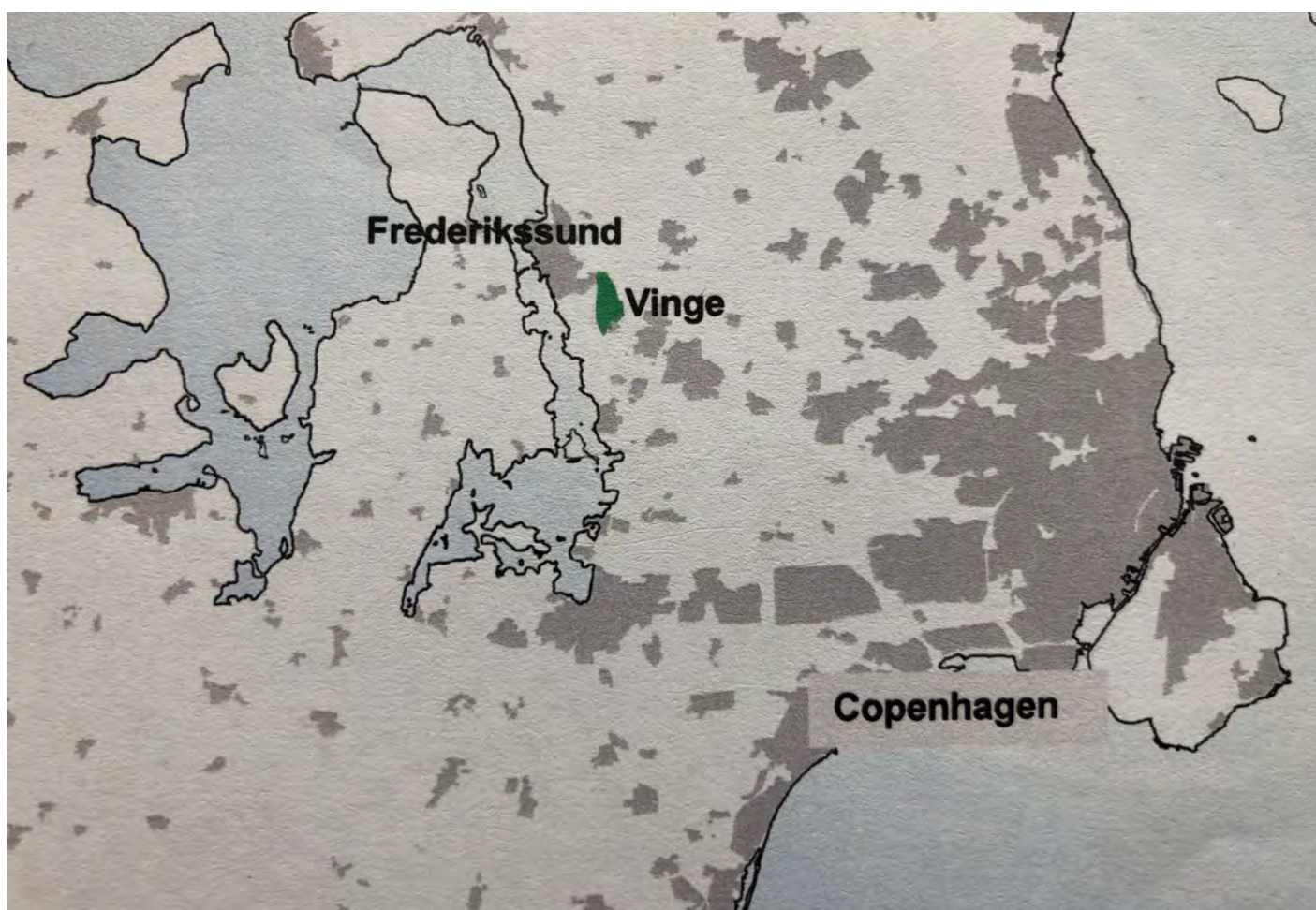
to year, secured by supply from a large solar thermal collector installation.

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**“In the Green Island project at Vinge North, there is used a new multi-layout thought process taking place, in that you replace the normal linear economic model (take, make, dispose) with a sustainable circular approach.”**

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To be certain all the heating and electricity needs are covered, local battery storage will also be used and







besides there is a backup supply of heat and electricity from generators that utilise locally produced biogas, coming from wastewater and organic waste. As a second and third priority, the use of a local gasification unit and use of certified biogas-based gas coming from the gas grid.

**“The vision is to obtain 100% of the energy supply from renewable energy in a cost-effective way for the inhabitants there. This will, in practice, mean use of both wind and solar energy in the area, therefore, supplying the main part of the energy needs.”**

In the Green Island project at Vinge North, there is used a new multi-layout thought process taking place, in that you replace the normal linear economic model (take, make, dispose) with a sustainable circular approach.

And this new way of thinking benefits from the fact that in Denmark, where almost 60% of all buildings are supplied by district heating, there is now a challenge to make a transition to a much more electricity-based district heating model, due to the high supplies of wind energy during long periods of time. This has been agreed by all political parties in Denmark and the laws and regulations have now changed accordingly, so it becomes beneficial to introduce heat pumps on a large scale in connection with district heating systems.

In many cases, this can also include use of the mentioned ATES technology, which the Danish company Enopsol has long-term experience in and is preparing a new project for the village of Kyndby Huse, also situated in the municipality of Frederikssund, where 160 existing housing units will be

equipped with local heat pumps in combination with an ATES system, at a total investment cost of €20,000 per housing unit.



**Peder Vejsig Pedersen**

**Senior Advisor, MSc**

European Green Cities

Tel: +45 2046 6755

[pvp@greencities.eu](mailto:pvp@greencities.eu)

[www.europeangreencities.com](http://www.europeangreencities.com)

[www.greenisland.dk](http://www.greenisland.dk)

[www.twitter.com/Vejsig](https://twitter.com/Vejsig)





# The future of the renewable energy market in Asia

The future of the renewable energy market in Asia is explored here by VHR Global Recruitment, including a focus on Taiwan's ambition to phase out nuclear power by 2025

Asia's renewable energy sector has been growing steadily over the last few years. Economic growth has exceeded 4% year on year and due to rapid urbanisation and industrialisation throughout the region, energy consumption has doubled since 1995. Needless to say, this has driven up energy demands at a prodigious rate. Because of this, green energy production is growing in every sector. Solar, wind and hydroelectric energy are more stable than traditional fossil fuels and are helping to lower air pollution in the area. We know that a 100% green energy future is possible and that the renewable energy market creates more jobs than the fossil fuel industry loses. But what does this mean for Asia and how is the region building its renewable energy infrastructure?

## How Asia's renewable energy sector has grown

Asia's renewable energy capacity has nearly doubled in the last five years, making up a significant chunk of the global supply of 2,351 gigawatts. This is roughly a third of the world's total energy and this number is growing all the time as more renewable energy enters the system and older fuel sources are phased out. Over 2018, Asia accounted for 61% of new renewable energy installations, proving the region is a powerhouse for development and implementation.

## China's role in green energy

The majority of renewable development in the area comes from China. In 2018, China accounted for 20 Gw



generated just through wind power alone. The total amount of global energy generated by wind power now stands at 564 Gw. As one of the most reliable methods of generating energy, it's not surprising that it is predicted to be one of the fastest growing energy supplies as we move into a post-nuclear future.

## Post-Nuclear Taiwan

Taiwan is one country planning on phasing out nuclear power by 2025, an ambitious target as around 15% of the country's energy is currently generated through this method. However, due to a recent referendum, it was revealed that 44% of Taiwan mistakenly believed that the majority of their energy supply came from nuclear sources and so voted to maintain the country's nuclear power stations. The government is continuing with the planned phase-out of nuclear power despite this vote, as General Electric no longer supplies some of the critical parts of these systems, making maintenance difficult. Beyond that, the issues surrounding nuclear pollution and safety are of paramount importance to those who live near the stations, who campaigned for their discontinuation.

There is a similar plan to phase out coal power by 1% a year, until the country no longer relies on the outdated fuel source for 40% of their energy needs. However, it is possible the country may suffer power shortages if there isn't sufficient investment in green energy.

Wind energy is going to be significant in Taiwan's future. But which method of production will they use?

## Horizontal versus vertical integration in wind power

Wind-turbine projects choose between two methods of production. Some tend towards using external suppliers and buy outsourced components to assemble their turbines. This is known as the horizontal integration strategy. Others go in the opposite direction and build components themselves, known as vertical integration.

It is likely we'll see a combination of both practices in Asia and Taiwan specifically. Taiwan has the technological capabilities for vertical integration, which allows for complete control over the installation. However, this does require a large amount of in-house manufacturing for new parts.

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**“Taiwan is one country planning on phasing out nuclear power by 2025, an ambitious target as around 15% of the country's energy is currently generated through this method.”**

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On the other hand, horizontal integration can bypass high production costs, while not compromising on quality. Specialised manufacturers can provide new machines on a large scale, which Taiwan will need to ensure it isn't left without sufficient energy for its citizens.

Having a mix of both practices allows for Taiwanese engineers to learn vital skills and develop their careers, while also ensuring investment in infrastructure around the country. ■

## Jack Terry

### Copywriter

VHR Global Recruitment

Tel: +44 (0)207 500 7980

V-HR.com

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# An underwater topographic survey for Taiwan offshore wind farms

An underwater topographic survey for Taiwan offshore wind farms is detailed here by Gwo-shyh Song, Associate Professor at the National Taiwan University

Concerning the development of an offshore wind farm in Taiwan, the first data obtained is from the underwater terrain or the so-called bathymetric measurement. Based on this data, we can map the topographic map under the water. Designers will, therefore, can determine the location of each wind turbine foundation based on this underwater topographic map. According to modern construction technology, the maximum depth of the foundation is only located at 50 metres deep. It is more difficult is to construct in a place where the depth of water is only 50 metres deep so this increases the cost.

But the measurement of underwater terrain is not just to understand the depth of the wind turbine location, because all power produced by the wind turbine must be transmitted by the power cable to the electricity generated by the transmission line into the grid for distribution. As a result, on the western offshore of Taiwan, in addition to the construction of hundreds of wind turbines placed on the seafloor, there will be electric cable network fitted between the foundations and cable routes extended from the sea to the land.

Many wind farms developed in Taiwan are located offshore. Their position is dozens of kilometres away from land and covers a very large area. There-

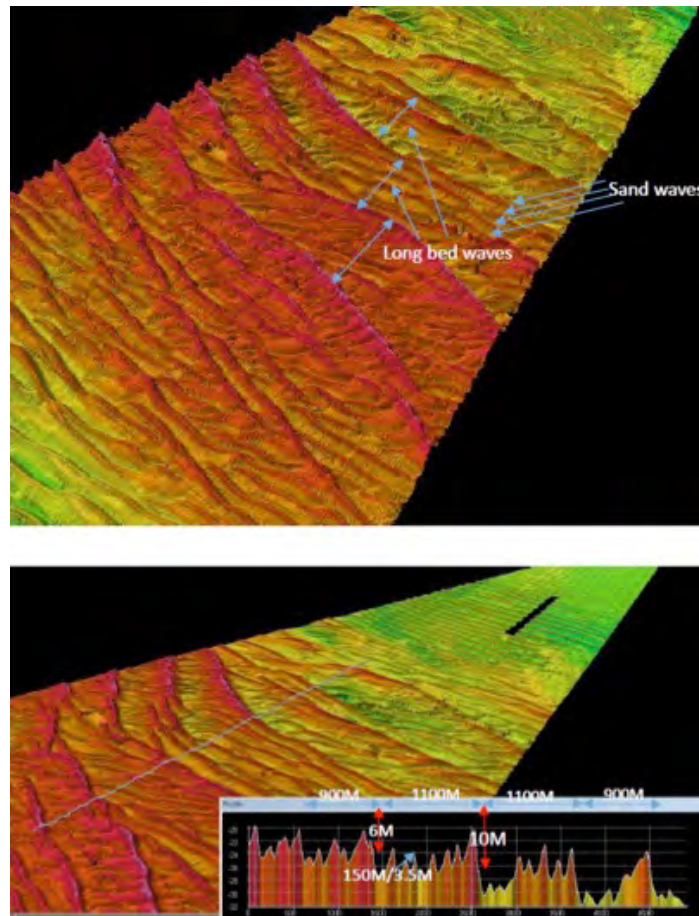


Figure 1: 3D underwater topography showing sand waves feature in F3 site 11th region

fore, for the proper laying of these cables, it is necessary to conduct a very accurate bathymetric survey to obtain a high-resolution data set from a wide area. The equipment used here is called multibeam echo sounder. Unlike single beam sounders, multi-beam systems use beamforming to extract directional information from the returning sound waves, producing a swath of depth readings from a single ping. The full swath across the

survey track includes a narrow track and forms over hundreds of multiple receive beams that are so narrower less than 1 degree depending on the system. With this design, with these collected data, it usually can map shipwreck, sand waves and pipeline using 3D visualisation technique.

With these cables laying on the seabed, there are several key points that must be noted:

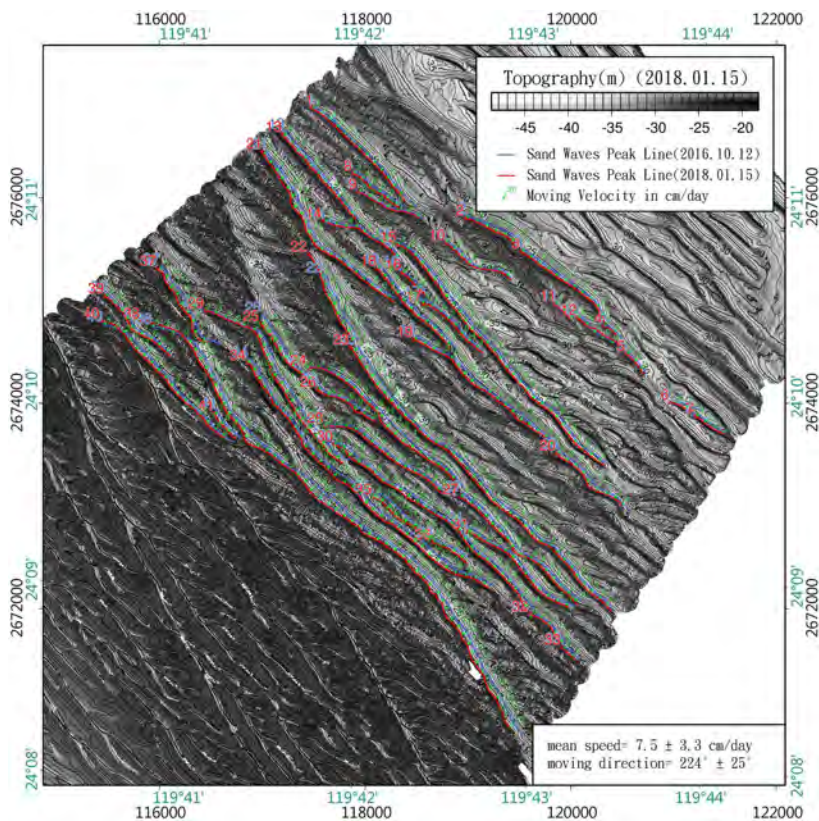


Figure 2: Sand waves motion vectors in F3 site 11th region

- The shorter the distance the cable is laid, the more the cost of construction can be reduced;
- To protect the cable from the activities of fisheries, the cable is spread over the sandy seabed and covered with sediments, in addition to the biological reef or rock area;
- Cable do not pass through areas with large terrain slopes, such as steep slopes or soft places, where earthquakes can easily produce a landslide or slump to break the cable, or where in large sand waves territory, the direction of parallel sand waves must be laid so that the cables do not span between the waves and hang on to the seabed;
- In places where the topography of seafloor is prone to topographic changes, the characteristics of terrain changes must be understood for the laying of cables; for example, there are a series of sand waves in Taiwan Strait area, which move

forward or in the direction of the bottom current.

In the wind farm areas of the Taiwan Strait, after previous surveys, because there are strong bottom currents in the area, over half of the wind farms have large sand waves (or dunes) shown on the seabed, shaped with more than hundreds of metres long and 10 metres or about three stories high.

Take the Formosa III (F-3) Wind Farms as an example; this wind farm is located in the central western Taiwan offshore or northern area of the Penghu Island. It occupies three areas, each of which is around 100 square kilometres and a development license has been applied for here by Macquarie Investment Management Limited. Hence, it covers an area around 280 square kilometres and its west margin is over 70 kilometres away from the coastline of Taiwan. They are scheduled to install about 170 6M watts wind turbines so that the devel-

opment of power generation can go to one gigawatt of electricity.

Global Aqua Survey Limited was commissioned by Macquarie to investigate the migration of sand waves in the F3 Wind Farms area. As a result, in 2016 and 2017, the Reson's SeaBat 8101 multibeam echo-sounder was used to collect the bathymetrical data in the whole region.

Figure 1 shows the underwater topographic map of the 11th wind farm in F3 area, where the vigorous development of sand waves can be seen in the area with a depth of 20-30 metres. In the area, there are many groups of long bed waves 1 kilometre long and 6-10 metres tall, covered with sand waves 150 metres long and 3.5 metres tall on the surface of these long bed waves.

In order to analyse whether these sand waves will move, one kind of presentation resulting from the variance analysis of the two-year data is shown in Figure 2. This picture uses some motion vectors to show how the sand waves moved within the area and indicate that the sand waves moved in southwestern direction at a mean speed of 7.5cm per day or 27.4 metres per year in that period of time.



**Gwo-shyh Song**  
**Associate Professor**  
 National Taiwan University  
 Tel: +886 (0)930 053 046  
 Gwoshyh007@gmail.com &  
 songs@ntu.edu.tw  
[www.oc.ntu.edu.tw/oceng/?page\\_id=24](http://www.oc.ntu.edu.tw/oceng/?page_id=24)



# Japan: A glimpse into environment and energy issues

The work of the Ministry of the Environment and Ministry of Economy, Trade and Industry in the Government of Japan are examined here

The Ministry of the Environment (MOE) Government of Japan is headed up by Yoshiaki Harada, Minister of the Environment. <sup>(1)</sup> The Ministry is responsible for global environmental conservation, nature conservation and pollution control. <sup>(2)</sup>

## Greenhouse gases

When it comes to the Ministry's policy on the global environment, one aspect of this concerns World Data Centre for Greenhouse Gases (WDCGG; a World Data Centre (WDC) of the World Meteorological Organization (WMO) which has been in operation since 1990 by the Japan Meteorological Agency (JMA). As the only WDC that specialises in greenhouse gases, it archives, collects and distributes data gases, such as CO<sub>2</sub>, CH<sub>4</sub>, CFCs and N<sub>2</sub>O and other related gases in the atmosphere.

In March 2019, WDCGG commenced the online provision of CO<sub>2</sub> observation data\* from Japan's Ibuki Greenhouse gases Observing SATellite (GOSAT) for April 2009 <sup>(3)</sup>, in addition to existing surface-based data, more of which the website goes on to explain.

"Integration of remote sensing satellite data and existing surface-based in situ data is expected to promote the wider use of this information and facilitate long-term monitoring of global distribution and sub-continental CO<sub>2</sub> emission/absorption estimates.

"WDCGG plans to continue improving its services for the collection, archiving and distribution of satellite data worldwide, including for GOSAT-2 (the successor to GOSAT), to support the monitoring of climate change and assist policy making, thereby helping to reduce environmental risks to society." <sup>(4)</sup>

## Climate change

The Ministry of the Environment notes that as climate change impacts have manifested in parts world, the Summary for Policy-Makers of the Intergovernmental Panel on Climate Change (IPCC)'s 1.5°C special report issued in October 2018 says that: "Global warming is likely to reach 1.5°C between 2030 and 2052 if it continues to increase at the current rate."

In addition, at the 24th Conference of the Parties to the United Nations Framework Convention on Climate Change (COP 24) held in December 2018, the Paris Agreement implementation guidelines were adopted and commonly applied to all Member States and highlight the importance of countermeasures against the further increase of global warming. The website of MOE develops this point further when promoting hold their International CCUS Symposium for Low-Carbon Society' that took place in February 2019.

"However, in order to realise a decarbonising society, not only the extension of conventional efforts but also new innovation are necessary. In addition, such innovations are now considered to be a source of growth.

"Under such situations, the Ministry of the Environment (MOE) has proceeded with technical demonstration projects of CCUS (Carbon dioxide Capture, Utilisation and Storage) which can greatly reduce CO<sub>2</sub> from large-scale emission sources to the atmosphere." <sup>(5)</sup>

## The plastic waste issue

Continuing the environmental theme of this article, we find out on the website of the Ministry of Economy, Trade and Industry (METI) that they have come up with the 'Roadmap for Popularizing Development and Intro-

duction of Marine Biodegradable Plastics', to deal with the issue of plastic waste. This compiles the expected major challenges in and measures for encouraging businesses to popularise the introduction of marine biodegradable plastics. We read more about this important aspect of energy policy on METI's website, in that is united the efforts of the public and private sectors by focussing on technical, economic and institutional challenges in giving direction for developing new materials and technologies that are biodegradable in the marine environment. <sup>(6)</sup>

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**“As for the electricity supply and demand for the summer of FY2019, a reserve margin of 3%, which is the minimum ratio required for a supply of electricity across Japan, is expected to be secured.”**

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By way of background information, it is worth noting here that Mr Hiroshige Seko is Japan's Minister of Economy, Trade and Industry. <sup>(7)</sup> The Ministry of Economy, Trade and Industry (METI) focuses on a wide range of policies, including economic & industrial policy, external economic policy and energy and environment policy. <sup>(8)</sup> Let's look at a further examples of this now.

### Electricity supply and demand

One interesting policy area METI highlights concern the results of the electricity supply and demand for the winter of FY2018, plus data on the outlook and measures for electricity supply and demand for the summer of FY2019. The Electricity and Gas Basic Policy Subcommittee, under the Electricity and Gas Industry Committee of the Advisory Committee for Natural Resources and Energy, compiled the data. More of this is explained by METI, which includes a call for citizens to cooperate in energy-saving efforts and the study of supply and demand of electricity during the summer and winter.

“As for the electricity supply and demand for the summer of FY2019, a reserve margin of 3%, which is the minimum ratio required for a supply of electricity across Japan, is expected to be secured.

“Aiming to provide full-fledged electricity supply-demand measures to address Japan's situations

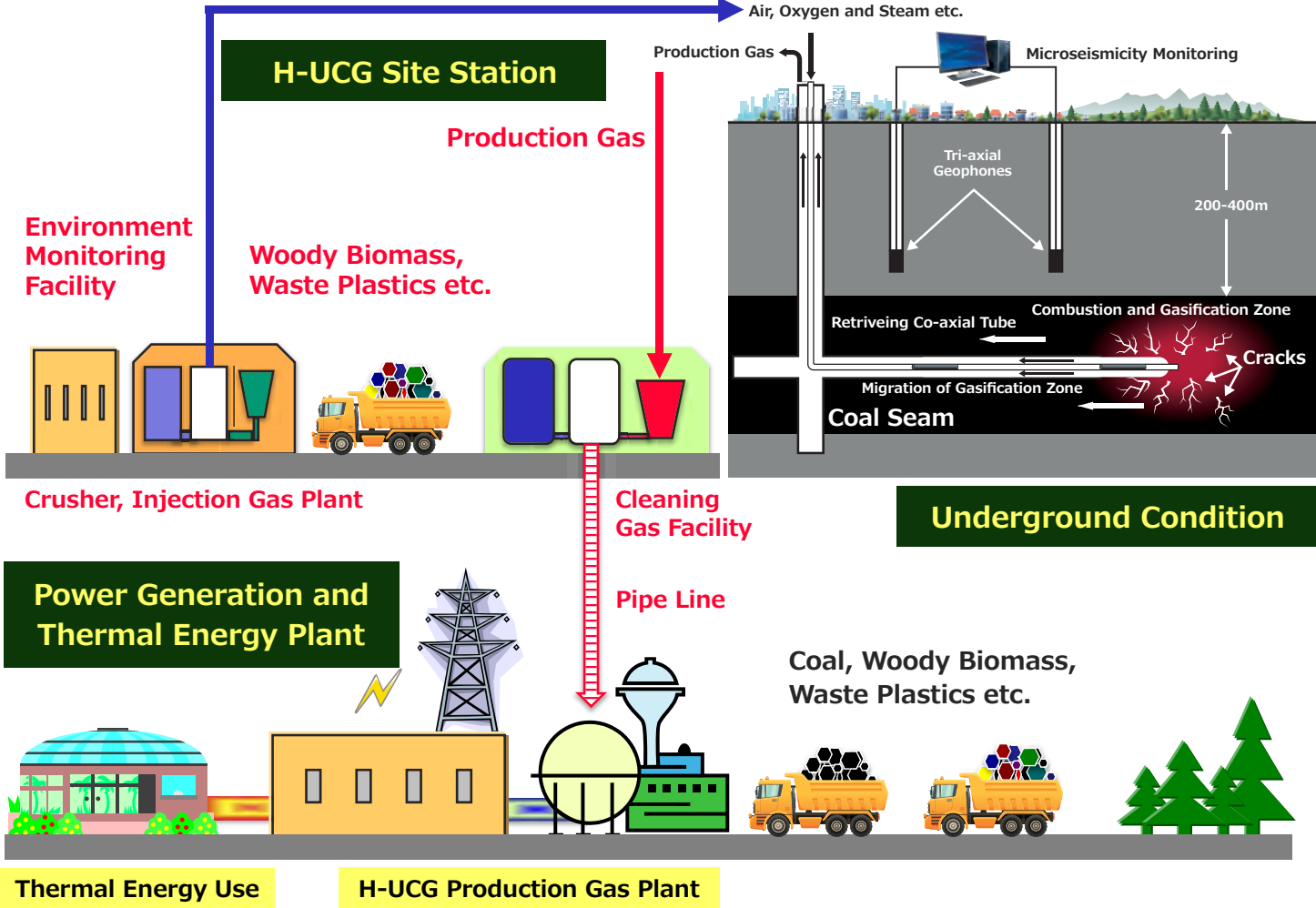
surrounding electricity after the Great East Japan Earthquake. Japan has been studying supply and demand of electricity in summer and winter, the seasons when electricity demand increases across Japan.”

One of the key points here is that the subcommittee decided not to request the cooperation of the public in energy conservation during summer 2019. Having said that, METI still wishes the public to cooperate in energy-saving efforts and conservation measures to help the environment at a reasonable pace, as has been the case in Japan for a number of years now. <sup>(9)</sup> ■

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# H-UCG (Hybrid Underground Coal Gasification) Project for Local Energy Source in Japan

Ken-ichi ITAKURA, University Professor at the Muroran Institute of Technology, introduces a project that concerns the current energy situation in Japan and the problems associated with this

Firstly, when it comes to the energy situation in Japan and its associated problems, almost 99% of coal is imported from foreign countries due to the current economic conditions. However, much un-mined coal remains in the country under difficult conditions to mine it out, since the geological conditions here are severe and have many faults. As such, UCG (Underground Coal Gasification) techniques are applicable.

## Problems of conventional UCG system

The conventional UCG process has had problems to overcome when applied to the coal seam of Japan.

One of the problems is gas leakage towards the surface through the cracks. Secondly, is subsidence caused by the UCG cavity in the coal seam. A third problem is groundwater contamination. These problems are induced

by the fracturing activity during UCG process.

### Hybrid UCG (H-UCG)

We have developed a safe, higher gasification efficiency and environmentally friendly UCG system. To solve the above problems caused by the fracturing of coal and rock, we apply acoustic emission/microseismic activity (AE/MS) monitoring techniques to visualise the combustion



and gasification reactor and control the fracturing activity using injection agents from the surface.

### Key technologies of H-UCG

#### Higher gasification efficiency

In spite of co-axial type UCG, to retrieve horizontal co-axial UCG achieves higher gasification efficiency which is the same as a conventional UCG system. It is a lower cost system.

#### A safe and environmentally friendly system

By controlling the fracturing in the coal seam and rocks by AE/MS monitoring during UCG, it is possible to visualise the underground gasification reactor and its safe operation.

#### Total environmental monitoring

Using the internet, all environmental data is remotely monitored – the air, the ground surface, underground and on groundwater.

#### Safe and continuous handling of UCG production gas

Discharge plasma units decomposed the production gas continuously, such as hydrogen sulfide.

### H-UCG

Woody biomass chips and waste plastic chips are gasified in an underground reactor. These chips are also used to control the temperature of the reactor.

#### CO<sub>2</sub> storage into the UCG cavity

When the process is finished, CO<sub>2</sub> gas is stored permanently inside the UCG cavity with a paste mixture. It contributes to the CO<sub>2</sub> reduction and supports the UCG cavity.

#### Benefits of our project

- It provides a local energy source for the energy grid.
- It gives a stable production of power and a thermal energy supply to the local area in an environmentally friendly and safe process.
- It provides a low-cost form of energy production.
- The usage of UCG produced gas has some flexible options to fit in with local needs.

#### Invitation of sponsors and partners

Now, we are planning the feasibility field experiments to evaluate the

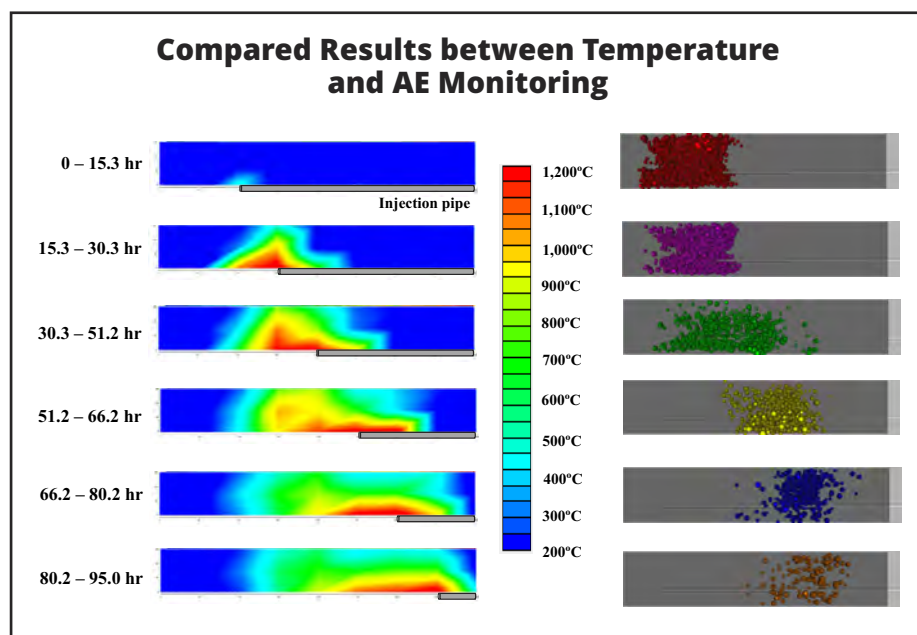
technology on safe and efficient gasification efficiency, in an economic way. To realise this field experiment, we are seeking sponsors and partners.

#### Recent publications

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**Ken-ichi Itakura**  
**Specially Appointed Professor**  
 Endowed Research Laboratory of Un-mined Mineral Resources and Energy Engineering  
 Muroran Institute of Technology  
 Tel: +81 143 46 5424  
 itakura@mmm.muroran-it.ac.jp  
<https://www.uri-net.com>

# Active safety: Paving the way for safe and efficient autonomous mobility

David Paja, Senior Vice President and President, Advanced Safety & User Experience at Aptiv, provides his opinion on active safety and how this is paving the way for safe and efficient autonomous mobility

It's the heart-stopping moment that almost every motorist will be familiar with – a split-second lapse in concentration, an unexpected distraction or straightforward error of judgement while we're at the wheel. In most cases, it involves nothing worse than a near-miss and a swift and timely reminder to keep our eyes on the road. Occasionally, however, the consequences of letting your mind wander whilst at the wheel can be tragic for both drivers and pedestrians.

There's no hiding that roads have become more crowded, drivers more distracted and, therefore, people causing more accidents. According to data from the National Highway Traffic Safety Administration (NHTSA), 94% of accidents are directly related to human error. In fact, a staggering 1.25 million deaths annually are caused by vehicles, according to the World Health Organisation (WHO). That means every 30 seconds, someone dies in a car accident. However, there are many reasons to be optimistic as governments and the automotive industry are looking to drastically reduce these figures. Most recently, the European Parliament has given the green light to new minimum European Union (EU) vehicle safety requirements that will come into force from 2022.

In an effort to make roads safer across the region, the EU's plans will mean by 2022, new active safety technologies will become mandatory in European vehicles to protect passengers, pedestrians and cyclists. With these plans, the safety performance of cars, light commercial vehicles, buses, trucks and trailers will be vastly improved. It's hoped that these new safety features will help reduce the number of fatalities and road incidents caused by human error by 90%. This initiative strongly supports the EU's long-term 'Vision Zero' goal which looks to greatly reduce road fatalities and serious injuries by 2050.

## What is 'active safety'?

In short, active safety is the use of technology to create a car that senses risk and either proactively alerts the driver to the potential danger or automatically takes the appropriate corrective action. This is a shift from the past, where the focus was primarily around trying to mitigate the damage caused by an accident. Previously, the automotive industry was concentrated on 'passive safety' systems, for example, seatbelts and airbags – where the technology worked to keep passengers protected during a crash. Now, thanks to innovation in technology we can proactively prevent crashes.

Some of the mandatory, active safety feature in the new regulation by the EU include lane-keeping assistance, advanced emergency braking and crash-test improved safety belts. In addition, new technologies will be able to detect driver drowsiness and distraction, for example, the sensors will identify when you are using a smartphone whilst driving, which fundamentally comprises the safety of the vehicle and its passengers.

## Making active safety mainstream

In a remarkably short space of time, this active safety philosophy has moved from the design lab to the public road. Today, safety systems such as emergency braking, lane assist and blind spot warning have become increasingly commonplace not just on premium brands, but mainstream models too. The implications of this are truly profound. When it comes to accidents, it's been calculated that just a half-second improvement in reaction time could prevent 60% of all the road traffic accidents that take place.

Technologies like adaptive cruise control, which adjusts the speed of your car if the car in front of you slows down, lane keeping systems, which alert you if you



start to veer out of your lane and emergency braking, which stops your car even if you don't – can all decrease the severity of crashes or prevent accidents completely.

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**“There's no hiding that roads have become more crowded, drivers more distracted and, therefore, people causing more accidents. According to data from the National Highway Traffic Safety Administration (NHTSA), 94% of accidents are directly related to human error. In fact, a staggering 1.25 million deaths annually are caused by vehicles, according to the World Health Organisation (WHO).”**

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Creating an active safety system that can be relied on to do exactly the right thing, at the right time, in all potential situations and scenarios, is a truly demanding challenge and one the EU is hoping to set the European automotive industry.

As an example of developments in the industry over the last 20 years, we were the first to put radar on a car in 1999 and integrate a multi-domain controller for

Level 3 automated driving systems in 2017 but this has not been an easy journey in the world of advanced driver assistance systems (ADAS).

No matter how well-intentioned, humans will continue to make mistakes. As a result, the EU's General Safety Regulation will enhance public trust and acceptance of autonomous vehicles to support the transition towards truly autonomous driving. Following compliance with the EU's new regulations, we hope these mandatory safety requirements will be enforced on a global scale to change perceptions of road safety and ultimately, prevent road accidents to achieve 'Vision Zero'. ■

**David Paja**  
**Senior Vice President**  
**President Advanced Safety & User Experience**

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# ECR: Leaders in mobile ticketing and revenue inspection solutions

ECR design and develop smart solutions supporting transport operators across the globe. With unique hardware in the form of compact, all in one solutions, we help customers to ensure that every ticketing experience is seamless, reliable and easy

**E**CR design and develop smart transport solutions for the mobile environment. Does your onboard ticketing restrict you and your passengers? Would you like to cut out ticket fraud and chargebacks? Then we can help.

ECR Retail Systems is one of the longest-established mobile point-of-sale (mPOS) specialists in the world and offers a wealth of industry experience in delivering smart solutions to its clients across the globe.

Transport providers including National Express, Stagecoach, LNER, OBB, Big Bus are using our fully mobile technology the world over. From ticketing to onboard retail and hospitality, we produce every aspect of our systems in-house from conception through to final delivery. We even design and manufacture our own hardware, so that clients can rest assured that every solution we supply to them is the best on the market today.

Having become specialists in the transport sector, we set out to deliver a system that encompasses not only state-of-the-art software but also the very latest in hardware technology.

We offer compact and lightweight handheld terminals – developed by our experts for the mobile environment. Features include:

All-in-one design with an inbuilt printer, 2D QR scanner, contactless/mobile wallet card reader, RFID, ITSO accreditation, 3G/4G mobile network, Wi-Fi, HotSwap battery, carry case. The benefits are proven:

- Real-time ticket validation;
- Anti-fraud prevents pass-back and duplication;
- Customer app and bookings;
- All payment types;
- Real-time reporting and head office dashboards;
- Offline capability, with no loss of functionality.

Whilst selling, the focus is on processing transactions quickly and smoothly – also vital for the overall customer experience. TicketPoS connects with mobile network and Wi-Fi wherever possible and reverts automatically to offline mode when no signal is available. Users are able to continue seamlessly with operations, from ticket and revenue checks to selling onboard.



*Kate Hutchinson, Head of Sales*

Passengers can purchase and validate tickets & travel cards from print-at-home to physical tickets and e-tickets on any device.

In addition, our system has numerous clever features designed to close gaps, improve cash handling whilst facilitating the move to cashless payments wherever possible. It uses





GPS tracking to deliver real-time and pinpointed sales data delivered on a clear to read head office dashboard.

TicketPoS is cloud-based ensuring that it requires no specific browser or additional software and is accessible from any location by head office users with their individual login.

We support promotions, discounts, agents and commissions, along with multiple other benefits. Not least is the anti-fraud measure in our dynamic QR codes and features in the customer app, which has been designed to give the user complete control over their ticketing purchase, usage and travel.

The Go2 all-in-one contactless-enabled handheld device comes with ITSO accreditation and full PCI

compliance, approved EMV levels 1 and 2, for a fully secure solution that is ready to deploy.

The super compact GoFree device operates without a printer and can communicate with portable ticket printers where required. Ideal for validation and inspection, both devices operate with full Windows 10 Enterprise and offer users multiple functionality from equipment and safety checks with a full audit trail, to messaging to and from head office & other users.

TicketPoS fully supports self-scan, reducing pressures on onboard staff where required and is small enough to be carried with ease throughout the working day.

Looking further ahead, at ECR we are working continuously with our clients to identify market trends and new ideas to incorporate into our software and we are always pleased to be able

to deliver and help our clients enjoy the benefits of what our systems can do. This year, we continue focusing on giving independence and control to the customer, making the buying process even faster and easier than before. This is set to help ticket sales rise significantly across multiple transport types and we are excited about the opportunities this will offer us and our clients throughout the transport market and beyond.



**Kate Hutchinson**  
**Head of Sales**  
 ECR Retail Systems  
 Tel: +44 (0)7787 52 4109  
[kate@ecr.co.uk](mailto:kate@ecr.co.uk)  
[www.ecr.co.uk](http://www.ecr.co.uk)  
[www.twitter.com/ECRsolutions](https://www.twitter.com/ECRsolutions)

# A focus on battery development in Europe

EIT InnoEnergy is the industrial actor for the European Battery Alliance (EBA) and as such, they steer this activity. Here, Bo Normark, Thematic Leader Smartgrids & Storage, EIT InnoEnergy explains precisely why the EBA is the catalyst for battery development in Europe

Even as recently as 2017, few believed large scale battery production in Europe was possible. Today, it is a different story. Europe is on track to increase its battery production capacity 20-fold in the next seven years.

Launched in October 2017, the European Battery Alliance (EBA) is accelerating Europe's move to its battery future. The EBA brings together key stakeholders to foster innovation, collaboration and the greater development of battery technology. Designed to cover the whole supply chain; the EBA has members involved in mining, refining, materials, cell production, battery packs and recycling. This whole value chain collaboration allows advancements in one area to be adapted into other parts of the chain.

Since launching, the EBA has overseen a dramatic rise of activity and innovation in storage. This journey is set to continue with Northvolt, an EIT InnoEnergy backed start-up, due to bring online its battery production hub later this year. But that is not all; Poland has cell production facilities that will be expanded and Umicore are investing in a plant for battery materials. Finland has new mines underway and investment from BASF in a factory for battery materials.

The battery eco-system is thriving. Start-ups are springing up to deliver new innovations, the automotive industry has set aggressive electric vehicle (EV) targets and supply chains are becoming more experienced. Despite this, it still continues to track behind the Asian market. It is catching up and aims to overtake by 2025 delivering a real success story for the EBA.

Unlocking the value of the battery supply chain across Europe will require the involvement of the Commission,

member states and industrial players if it is to catch up and lead Asia. The automotive sector is a keen focus on battery innovations. At present, Europe is the leading exporter in the automotive sector – with more than 50% of the global export sales value. EVs are growing in popularity, as this trend continues, Europe needs to ensure it has leading capabilities in battery technology to at worst, reduce reliance on imports and at best to prevent losing market share to Asian car manufacturers.

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**“As the race continues to be the market leader in energy storage, the EBA, in a remarkably short space of time, has mobilised Europe to come together and drive success. This has boosted the confidence of European actors and member states to deliver the next wave of innovation in battery storage, enabling the continent to snap at the heels of its Asian competitors.”**

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However, EVs are not the only focus for the EBA. Exciting innovations are also being developed around the recycling of batteries. Being resource intensive, recycling is key for batteries to be truly sustainable. Less than half of portable batteries are currently recycled in Europe – a percentage the EBA wants to improve. The next EBA event will shine the spotlight on recycling so the whole supply chain can discuss what needs to change to improve the process.

Collaboration is central to the EBA as the bridge between member states and industry. This includes the EBA having the eyes and ears of the Commission, to make sure the Commission prioritises the right policies to support the continued growth of Europe's battery market. This collaboration idea extends into the possibility of having trusted partners supplying batteries for other products. As the market continues





Bo Normark

Developments in new markets could shake up the existing industry too. Lithium-ion batteries are currently king in the battery space. But this reign won't be forever, especially in stationary batteries. Developers are increasingly keen on longer duration batteries and those capable of more cycles. This desire, plus the need to move away from precious metals, is likely to spur greater innovation in stationary battery types, all under the watchful guidance of the EBA.

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**“Unlocking the value of the battery supply chain across Europe will require the involvement of the Commission, member states and industrial players if it is to catch up and lead Asia. The automotive sector is a keen focus on battery innovations. At present, Europe is the leading exporter in the automotive sector – with more than 50% of the global export sales value.”**

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As the race continues to be the market leader in energy storage, the EBA, in a remarkably short space of time, has mobilised Europe to come together and drive success. This has boosted the confidence of European actors and member states to deliver the next wave of innovation in battery storage, enabling the continent to snap at the heels of its Asian competitors. ■

to be a hive of activity, utilising established factories and production facilities can help to quicken new innovations to market.

And innovations are flourishing. EIT InnoEnergy's recent [Global Call for Start-ups](#) in the electrical storage space highlighted advancements in fast charging, portability and reduced costs, to name just a few. From over 200 global applicants, the final 10 were all European based start-ups – a testament to the hotbed of innovations in the region. Across Europe, companies are developing and refining current technologies, while others are looking for longer-term solutions to revolutionise the sector; both have one eye on new markets.

Brand new fields are becoming potential storage markets. The marine sector is looking to electrification. This provides a significant opportunity to develop capabilities for a new sector that needs to reduce its carbon footprint. Shipping provides unique challenges and opportunities for those looking to develop new technologies, such as battery duration and at-sea charging potential.

### **Bo Normark** **Thematic Leader Smartgrids & Storage**

EIT InnoEnergy

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# The priorities of the internal market, industry, entrepreneurship and SMEs in Europe

The priorities of Elżbieta Bieńkowska, the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs are charted here, including her thoughts on social innovation

**E**lżbieta Bieńkowska is the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs. She is in charge of renewing the strategy for completing the single market, for goods and services such as extending the list of products to be recognised throughout the European Union (EU). She also has to reinforce a strong and high-performing industrial base for our internal market, by encouraging investment in modern technologies to improve the business environment. Identifying new possible job sources, particularly with a focus on high-value jobs in start-ups, and encouraging the EU States to make efficient defence markets is another key element of her work.

## Supporting shipbuilding and other industries

In the view of the European Commission, the European shipbuilding industry is a competitive and dynamic sector. Certainly, from an economic and social perspective, it is important, yet it is also linked to other sectors including transport, energy, security, research and the environment. While shipbuilding is a strategic industry in various EU countries, the sector faces fierce international competition from countries like China and South Korea. We learn more about this challenge now in the words of the European Commission.

“The industry has also suffered from the absence of effective global trade rules and state supported over investment. This is because shipyards offer a wide range of technologies, employ a significant number of workers, and generate foreign currency income, due to the fact the global shipbuilding market is dollar-based.”

On the positive side, we know that shipyards (there are about 150 large shipyards in Europe with some 120,000 employed in them) make a significant contribution to

national security interests (military shipbuilding) and regional industrial infrastructure. The Commission promotes the development of this industry and address competitiveness issues that occur.

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**“The European Commission is committed to empowering youth in shaping a better future for themselves, their communities and Europe at large. The winning projects can deliver on this goal in a sustainable way which will be beneficial for both the economy and society at large.”**

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So what is the Commission doing to address issues affecting the shipbuilding industry? They are achieving this through a variety of policy measures, especially, [LeaderSHIP 2015](#) and [LeaderSHIP 2020](#).<sup>1</sup>

Early on in her time in this role, the Commission set out a strategy for revival of European industry, which set out to focus on competitiveness in terms of the preparation of trade agreements and policy proposals. The Commission also adopted strategies and industrial plans targeted at stimulating growth, innovation and boosting competitiveness in sectors like shipbuilding and industrial products, automotive manufacturing and commodity markets.<sup>2</sup>

More recently, a high-level conference on tourism was held at the European Parliament, according to the European Travel Commission who are funded by the EU. While growth and employment are key priorities for the EU, we find out that tourism is a vital sector because it accounts for 10% of GDP and jobs in Europe. In addition, it also generates growth in many key sectors, such as shipbuilding, construction, cultural and creative industries, retail, transport and textiles. 5 million new jobs related to tourism are expected to be created in the EU over the next ten years, with 20% of those jobs

going to people under 25, therefore, tourism will play a key role in combatting youth unemployment.<sup>3</sup>

## The development of social innovation

Elżbieta Bieńkowska is also interested in the development of social innovation within the EU. In 2018, the European Commission held an awards ceremony in Brussels to recognise outstanding projects that develop and showcase social innovations from throughout Europe. Each winner received a €50,000 prize to enable further development and lasting, real implementation.

The 2018 theme was 'RE:THINK LOCAL', which encouraged participants to tackle local challenges in their changing economy in order to create opportunity, particularly for the younger generation. The winners were:

- **Ulissee:** A digital travel platform for deaf people.
- **HeritageLab:** An incubation programme for young people who want to set up a business.
- **Career Bus:** A career orientation venture for young people from small urban and rural areas.

But the Impact Prize money was awarded Mouse4All (Spain), a project that enables people with severe physical disabilities to access an Android tablet or smartphone without touching the screen. This kind of social innovation is increasingly necessary as digitalisation and globalisation increases, connecting the world in a way that inspires new dimensions for innovation. Commissioner Bieńkowska said: "They create opportunities where most only see challenges.

"The European Commission is committed to empowering youth in shaping a better future for themselves, their communities and Europe at large. The winning projects can deliver on this goal in a sustainable way which will be beneficial for both the economy and society at large."<sup>4</sup>

## Protecting small and medium-sized enterprises (SMEs)

The Commissioner also focuses on her duty to SMEs as SME Ambassador, participating in the creation of legislation to regulate the Digital Single Market. In February 2019, the European Commission aims to protect

the online business environment for small businesses who may suffer from any unfair trading practice – especially structural issues on online platforms that can undermine the innovation of the SME via an arbitrary suspension of an account, a lack of transparency in platform rankings and a more meaningful dispute resolution method that involves mediators. This initiative intended for all EU online platforms stems from the Commissions Communication on Online Platforms of May 2016 and implements President Juncker's 2017 State of the Union address.

Bieńkowska, explaining her philosophy of this approach, said:

"Our new rules are especially designed with the millions of SMEs in mind, which constitute the economic backbone of the EU.

"Many of them do not have the bargaining muscle to enter into a dispute with a big platform, but with these new rules they have a new safety net and will no longer worry about being randomly kicked off a platform, or intransparent ranking in search results."<sup>5</sup> ■

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# FIBRESHIP Project: The greatest challenge for the future of European shipping and shipbuilding

FIBRESHIP is a revolutionary European R&D project which attempts to develop a new market focused on the design and construction of large commercial vessels in composite materials to benefit the future of the European shipping and shipbuilding industry

**T**he budget of the FIBRESHIP R&D project is greater than €11 million, most of which has been funded by the European Commission. FIBRESHIP (H2020, Grant 723360) is a revolutionary European R&D project which attempts to develop a new market TO focus on the design and construction of large commercial vessels in composite materials. For the project stakeholders, the use of composite materials results in a significant reduction in the structural weight of a vessel, which implies a reduction in energy consumption, as well as an increase of payload capacity and reduction in operation and maintenance (O&M) costs. This will hugely benefit the future of the European shipping and shipbuilding industry.

Today, most small vessels (below 50 meters length), such as leisure crafts, sailing yachts, or ferries are built using fibre-reinforced polymer (FRP) materials. However, the wide use of composite materials in the construction of large-length vessels is not permitted for the main structural elements of ships over 500 GT (approx. 50 metres in length) due to International Maritime Organization (IMO) regulations by means of SOLAS. This regulatory limitation is attributed to the low mechanical performance of composite

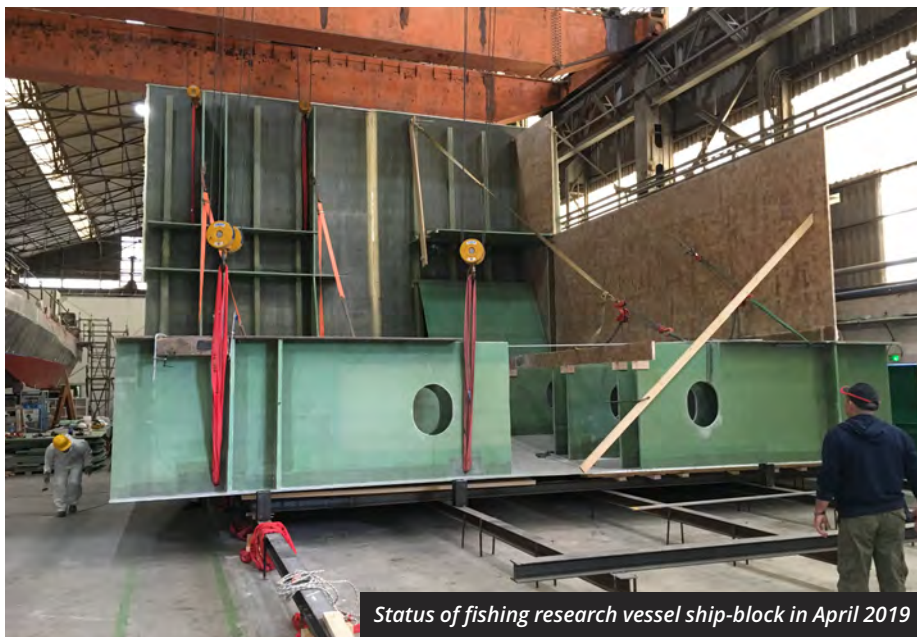
structures at elevated temperatures caused by fire events, which can compromise the safety of a vessel. In this regard, the major challenge of this project is to set in motion a new regulatory framework, which allows for the integral construction of large-length vessels made with composite materials, thus enabling its wide application in the shipbuilding industry.

The widespread use of lightweight composite materials in the design and construction of large-length vessels can considerably improve the performance and efficiency of vessels. From the materials perspective, the massive use of FRP in the construction of vessels will result in a significant lightweight reduction in a range of 30-40% with respect to conventional steel-based vessels. Moreover, the integral design in FRP will suppress the problems of corrosion, which is of critical importance to reduce vessel maintenance costs. From the energy point of view, the substantial weight decrease of the composite-based vessels causes a significant consumption reduction, which induces an important cost-saving in shipping. Consequently, FRP vessels might have a higher payload capacity when compared to standard steel-based ships, which is of vital importance for the practical applica-

tions of container ships and other transportation vessels. Last but not means least, the massive application of composite materials in the vessel design is expected to reduce greenhouse gas emissions and diminish the underwater radiated noise (URN), which is of utmost importance from the environmental perspective.

FIBRESHIP consortium is composed of an industrial network of 18 partners, all of whom play a critical role in the European shipbuilding and shipping industry. The partners are divided as follows: three certification companies (Bureau Veritas, Lloyd's Register and RINA), three medium-sized shipyards (ixblue, NAVROM, and TUCO), four research centres (CIMNE, SOERMAR, University of Limerick and VTT), four shipowners (ANEK, DANAOS, FOINIKAS and IEO), and four marine engineering companies (COMPASSIS, ATEKNEA, TWI and TSI).

The thematic areas analysed in the course of the FIBRESHIP are: (i) The shipping market and business analysis; (ii) Design and engineering; (iii) Material, components and modelling and; (iv) Production and life cycle management. The different tasks of the project are interconnected with each other, providing the required information for the thematic areas.



Status of fishing research vessel ship-block in April 2019

The shipping market analysis addresses the current situation of the market through a SWOT analysis and evaluates impacts, potential economic benefits and forecasts the widespread use of composites in the construction of ships over 50 metres length, preparing a roadmap of FRP adoption in the European Union (EU) shipping market. Additionally, a cost-benefit calculator is being developed to quantify the economic advantages which will bring the integral construction of large-length ships in composite materials.

An extensive experimental test campaign focused on mechanical, fatigue, and fire behaviour of the composite vessels has been performed to assess the performance of the composites used in fibre vessels. As a result, a composite material selection methodology for large vessels has been carried out, as well as a set of bonding techniques eligible to join ship modular blocks and structural parts.

As an important part of the project, the design of the three vessel categories most promising for market orientation (containership, ROPAX, and fishing research vessel) is being addressed, as well as the integration and develop-

ment of different developed numerical models in a unique tool to analyse structural behaviour and collapse events. Consequently, new design guidelines and standardisation rules will be developed based on fire and structural performance criteria.

Likewise, a production methodology to be adopted by shipyards to build FRP commercial vessels has been developed, considering modular subdivision and assembly sequencing recommendations to reach cost-efficient results. On the other hand, different strategies regarding inspection, life cycle and waste treatment for FIBRESHIP solutions are being addressed to evaluate the O&M costs.

Regarding test campaigns, a set of vibration and noise tests were performed in a 35m length vessel in FRP to validate URN models, a parameter of high importance to assess interferences at echosounders and effects on marine fauna, among others. In addition, a full-scale test has been carried out in a containership to validate the developed numerical models and to evaluate an innovative structural health monitoring strategy for FRP vessels in real time.

As a demonstrator of the achievements and technological breakthroughs of FIBRESHIP, a ship-block of the fishing research vessel (overall length of 85m) designed by TSI, is built at ixblue shipyard. The main purposes of the demonstrator are to prove the feasibility of the construction of a vessel in composites and verify the experimental and theoretical results obtained over the project in a real-scale module.

Thus, the major challenge of this project is to impulse a new regulation able to enable the use of composites in the structure of large-length vessels. The massive use of composites in the design and construction of large vessels will revolutionise the shipping industry due to its multiple economic and environmental benefits.

For further information, visit our website ([www.fibreship.eu](http://www.fibreship.eu)) or contact the FIBRESHIP Project Coordinator. In addition, the 2nd Public Workshop of FIBRESHIP will be held in Marseille on 25th June 2019 where you can learn more about our achievements in this project. Here, it will be possible to see and touch the above-mentioned demonstrator.



**Alfonso Jurado**  
**Head of R&D Department,**  
**FIBRESHIP Project Coordinator**  
 TSI – Técnicas y Servicios de Ingeniería S.L.  
 ([www.tsisl.es](http://www.tsisl.es))  
 Tel: +34 913 459 730  
[alfonso.jurado@tsisl.es](mailto:alfonso.jurado@tsisl.es)  
[www.fibreship.eu](http://www.fibreship.eu)  
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# How social innovation can support citizen participation

Beth Perry, Catherine Durose and Liz Richardson reflect on the findings of the Jam and Justice Action Research Collective in Greater Manchester

**D**efinitions of social innovation focus on social processes to generate new ideas that work to address unmet social needs. Innovations are social in their ends and in their means. Done well, social innovation can be one way of meeting global goals around meaningful participation in decision-making, recognised as a key priority for cities in the United Nations New Urban Agenda. But putting this into practice is tricky.

Greater Manchester, in the North of England, is a city-region with 2.8 million people. It was the first English city-region to agree a deal for greater devolved powers from central government. In 2017, residents elected their first Mayor to head up a new Combined Authority, with the ten local authorities. The deal was criticised for being made behind closed doors; many people asked how devolution could be an opportunity for greater citizen participation in addressing substantive policy concerns.

In 2016 researchers from the Universities of Sheffield, Manchester and Birmingham, with the Greater Manchester Centre for Voluntary Organisation, brought together an Action Research Collective (ARC) to co-produce ideas to tackle this challenge. Through the project Jam and Justice: Co-producing Governance for Social Innovation, the ARC set out to examine how cities could be governed differently.

A set of test-and-learn projects were initiated and rolled out from the ARC – on topics including spatial planning, energy policy, procurement, local democracy, youth engagement, political engagement, health and social care, digital innovation and the solidarity economy.

Through our work we offer fresh insights into three basic tenets of social innovation: its social means, novelty and ends. These confirm but also challenge conventional policy wisdom.

## Co-production means ‘social’ innovation processes

Co-production can make a positive contribution to socialising innovation processes. Co-production means taking diverse expertise seriously in the framing, design and development of policy. Social is not only being together but knowing together. Socialised processes of knowledge production enable the generation of ideas, free from the usual constraints of policy-settings. Co-production values citizens as experts alongside professionals or academics, and opens up what evidence is needed for policy.

The ARC’s projects used creative methods to open up policy imaginations. For instance, one project developed in collaboration with the Carbon Coop developed participatory energy walks around the city, ending with a pie and pint in the pub. The walks created public awareness and pressure to

open up policy agendas around the municipalisation of energy. The project also showed that social innovation is possible on technical issues, as well as areas usually reserved for public engagement.

One participant in our procurement project reflected that ‘if we take people that work in this field and create space outside their work, we create opportunities for new things to happen’. Across our projects we found that getting the right physical spaces and social interactions for social idea generation are key. Our projects engaged with citizens in open and ‘popular’ spaces rooted within neighbourhoods, as well as opening up privileged spaces usually reserved for officials.

## Social innovations are not always ‘new’

Politicians and decision-makers often cherish ‘new’ ideas. There is a lot invested in promoting places as cutting-edge and in the need to appeal to the electorate through emphasising a break with what went before, or to demonstrate distinctive value for funders (May and Perry, 2018).

Our ARC projects did generate original ideas, but also took inspiration from many sources. Sometimes ideas are new to a place or policy setting. Putting existing ideas into imaginative orderings and contexts is also a form of innovation. Policy should seek to





disincentivise reinventing the wheel by valuing learning and sharing in socialised processes.

We identified different social innovation practices that sit alongside the search for 'new' ideas: *Remembering* means looking to the past to learn from what has been tried, succeeded and failed; *Borrowing* involves adapting and testing existing models of citizen engagement in new policy and place-based contexts; *Translating* is important in ensuring that ideas can be acted on through communicating existing and new ideas in a relevant way to different audiences; *Synthesising* focuses on collating and integrating perspectives and ideas into new constellations; *Validating* can be useful in grounding existing policy, through engagement with the practicalities of implementation; finally, *Questioning* means reframing policy issues to open up new challenges and horizons.

## We need new ways to evaluate 'social ends'

Defining social innovation in terms of 'social ends' draws attention to the distribution of value resulting from innovation processes. Our ARC projects engaged more than 400 discrete individuals and led to a number of

evidenced changes to policies to bring urban justice issues into greater focus. Significant impacts include reframing policy ideas, seeding new models or approaches, infrastructuring relationships through new or strengthening relationships and changing mindsets by creating space for perspectives to shift.

A critical issue is how we develop metrics for evidencing and evaluating the outcomes of complex, messy, distributed social processes, like social innovation and co-production. As we argue in our article in *Nature* (Durose, Richardson and Perry, 2018), existing ways of measuring and evaluating co-production are inadequate. Long-term social processes enhance the importance of tracking impacts and outcomes to monitor intended and unintended effects.

Critically, we need extended peer communities to assess the value of social innovation and the extent to which social ends are met. What constitutes success? Who determines what 'ends' social innovation should meet? For social innovation to be part of the mix in realising global goals, citizens also need to participate meaningfully in assessing its outcomes.

## Find out more:

Read our interim report [Co-producing the City](#) here.

Or visit [jamandjustice-rjc.org/](http://jamandjustice-rjc.org/)

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## Professor Beth Perry Professorial Fellow

Urban Institute, University of Sheffield  
Tel: +44 7753 420 822  
[b.perry@sheffield.ac.uk](mailto:b.perry@sheffield.ac.uk)  
[www.urbaninstitute.group.shef.ac.uk](http://www.urbaninstitute.group.shef.ac.uk)  
[@TheUrbanBeth](https://twitter.com/TheUrbanBeth)

# The European Court of Justice and consumer protection

Trevor Tayleur, Associate Professor and Head of Design and Assessment at The University of Law, explains the work of the European Court of Justice and their work around consumer protection

The European Union's single market has given consumers access to a wider range of goods and services and has increased competition between businesses. The European Union (EU) has, therefore, passed a significant amount of legislation aimed at protecting the consumer. The areas in which the EU has legislated include:

- Distance selling, in particular buying goods online;
- Unfair contract terms, preventing businesses from enforcing unfair terms against consumers;
- Package holidays, making providers of package holidays responsible for the proper performance of all travel services included in the package;
- Product labelling, ensuring consumers are provided with comprehensive information regarding the content and composition of products to protect their health and interests.

Giving consumers rights without simultaneously providing them a means of enforcement would be pointless. EU Law has, therefore, developed a system which enables national courts to protect the rights of consumers. The European Court of Justice (ECJ) is at the apex of this structure which has involved a remarkable degree of cooperation between the ECJ and national courts. The EU Treaties have given the ECJ the task of ensuring that EU Law is observed throughout the EU, a task that the ECJ has embraced with enthusiasm. Even the best-drafted legislation requires interpretation and the ECJ has the power to provide authoritative interpretations. However, the ECJ has also needed the support of national courts.

There are two main means of enforcing EU consumer protection law. The first is private enforcement, where a consumer sues a retailer for breaching their rights under EU Law. The second is public enforcement, where national regulatory bodies take action against offending businesses.

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**“Whenever a case reaches a national court, the court will be under a duty to apply EU law to the facts. If the meaning of the relevant EU legislation is clear and undisputed, then the national court will simply apply it. If the meaning of the EU legislation is unclear, then the national court has the power to invoke the preliminary ruling procedure and may refer to the interpretation of the EU legislation in question to the ECJ.”**

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As regards private enforcement, individuals have very limited rights of access to the ECJ. If a business infringes their EU rights, they must take action before their national courts; they cannot take their case directly to the ECJ. Similarly, national regulators cannot haul businesses who act unlawfully before the ECJ; they must use national legal procedures. This means that national courts are frequently the main enforcer of EU Law and this does give rise to a potential difficulty.

There are, pending Brexit, 28 Member States, each with their own national courts responsible for applying EU Law. If the various national courts were to interpret EU legislation differently, this could undermine the single market. One of the basic principles of the single market is that cross-border trade should be as easy as trade within a single state. It should be as straightforward for a consumer in Paris to buy from an online retailer in Manchester or Warsaw as from one in their own country.



The consumer in Paris would expect EU Law on distance selling to be interpreted in the same way whether they were buying from an online retailer in Manchester or Warsaw. If the French, English and Polish courts were to interpret the law on distance selling differently, this would not be the case. Likewise, online retailers would find it very confusing if the rights of their customers varied depending on the Member State in which they lived. The EU Treaties have, therefore, developed a mechanism, the preliminary ruling procedure, aimed at ensuring the uniform and consistent application of EU Law in all Member States.

EU Law does encourage private enforcement. For example, in cross-border claims, consumers can sue a business either in the courts of their home state or the courts where the business is based. For small claims of up to €5,000, consumers may use the simplified European Small Claims Procedure. Realistically, though, it is often difficult and not cost effective for an individual consumer to take action against a large business. Accordingly much of the case law in the field of consumer protection has flowed from public enforcement action by national regulators. For example, a trading standards body may bring a criminal prosecution in a national court against a business that has flouted the

law or take other types of enforcement action against it. In the latter case, the business can appeal to the national courts.

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**“The preliminary ruling procedure has led to the ECJ giving many significant rulings in the field of consumer protection. For example, the ECJ has insisted that labelling must be clear, informative and not misleading. In the *Teekanne* case (2015), pictures of raspberries and vanilla flowers appeared on a packet of fruit tea. The tea itself contained neither as ingredients. Although the actual list of ingredients on the packaging was correct, the ECJ held nonetheless that the packaging was misleading as it gave the impression that the tea contained the ingredients depicted.”**

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Whenever a case reaches a national court, the court will be under a duty to apply EU law to the facts. If the meaning of the relevant EU legislation is clear and undisputed, then the national court will simply apply it. If the meaning of the EU legislation is unclear, then the national court has the power to invoke the preliminary ruling procedure and may refer to the interpretation of the EU legislation in question to the ECJ. In some situations, the national court must refer to the





question of interpretation to the ECJ. When the question of EU Law is one of general interest, it makes sense for the national court to refer it to the ECJ. If the national court decides not to refer to the question and interprets the relevant EU Law itself, there is a risk that it might interpret it incorrectly. Different national courts could arrive at different interpretations, leading to uncertainty and inconsistency in the single market. National courts have therefore as a rule been willing to refer questions of EU Law to the ECJ in cases of doubt. Once the ECJ has answered the question, the national court must apply the ECJ's ruling to the facts of the case.

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The ECJ has also clarified the rights of consumers where they claim to have received defective goods. In the *Froukje Faber* case (2015), the ECJ ruled that if a defect arises within six months of delivery of the goods, it is presumed that the goods were defective. The consumer has to prove that the defect arose within six months and, once proved, the retailer has to replace the goods.

The ECJ has also taken a firm stand against unfair commercial practices, ruling that aggressive marketing practices are unlaw-

ful. In the *Purely Creative* case (2012), the ECJ decided that it is not permissible for a business to give the impression that a consumer has won a prize when they have to incur expense to take up the prize. For example, where a cruise is offered as a prize, it is not permissible to require the consumer to pay extra costs such as insurance, port fees and the cost of food and drink during the voyage.

More controversially, in the *Tofu Town.com* case (2017) the ECJ ruled that plant-based products cannot be described by designations used to describe animal-based products such as milk, butter, cheese and yoghurt. Consequently, although there are some exceptions such as ‘coconut milk’, designations such as ‘soya milk’, ‘tofu butter’ and ‘plant cheese’ are not permissible.

Although the rights in these cases were created by EU consumer protection legislation and not by the ECJ itself, the ECJ has interpreted EU consumer protection legislation in a very consumer- friendly manner. This trend is likely to continue. ■

**Trevor Tayleur**

**Associate Professor and Head of Design and Assessment**

The University of Law

Tel: +44 (0)1483 216 000

[www.law.ac.uk](http://www.law.ac.uk)

[www.twitter.com/universityoflaw](https://twitter.com/universityoflaw)



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# ‘Linguistic Precedent’ in European Union Law

In the third in a series of five articles exploring the phenomenon of multilingual European Union (EU) law, Dr Karen McAuliffe, PI on the European Research Council funded project ‘Law and Language at the European Court of Justice’, discusses the concept of linguistic precedent in judgments of the Court of Justice of the European Union

This article is the third in a five-part series focusing on the ERC-funded project ‘Law and Language at the European Court of Justice’ (the LLECJ project) – read the previous articles [here](#) and [here](#). Today, we focus on the LLECJ Project’s second sub-project: the development of ‘linguistic precedent’ in judgments of the Court of Justice of the European Union (CJEU).

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**“Analysis of the various data collected has demonstrated that language does indeed play an important role in the development of a de facto precedent in CJEU judgments.”**

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Over the past 15-20 years, the development of a de facto precedent in European Union (EU) law has been the subject of significant academic debate, centring around questions of what it means for a supreme court to ‘make law’ and when it is possible to say that its decisions are ‘precedents’. While there is no official doctrine of precedent in EU law, the CJEU does on occasion appear to regard its previous decisions as establishing a law that should be applied in later disputes: ‘tying down’ national courts without establishing a formal hierarchy in the strict sense. Commentators, such as Komarek, Dougan, Chalmers, and Dyrberg have extensively explored and critiqued that concept. In EU law,

the development of de facto ‘precedent’ is inextricably linked to the procedure for references for a preliminary ruling under Article 267 TFEU. In developing the principle that its decisions have binding force on all national courts, the CJEU has based much of its reasoning on the need to ensure the ‘uniform application of EU law. The question raised by commentators researching ‘precedent’ in EU law is thus: what exactly is meant by uniformity? It is generally agreed that ‘absolute sameness’ is unachievable in any legal system; and that more ‘precedents’ do not necessarily mean more uniformity. According to Dyrberg, however, “uniform application is...a sort of existential problem to which the [Union] legal order has to relate” – i.e. that a presumption of uniformity is necessary for the CJEU to claim authoritative status within the EU legal order – which aims at supremacy of EU law rather than uniformity itself.<sup>1</sup>

There is, however, one important aspect of the development of a de facto precedent in CJEU judgments which has been thus far overlooked in the literature: the linguistic aspect. Development of the theory of linguistic cultural compromises in the [LLECJ Project’s first subproject](#) raised questions relating to the process behind the production of CJEU judgments, opening the door for further analysis

of the development of such de facto ‘precedent’, where, in theory, none should exist. The research questions investigated in the LLECJ’s second sub-project included:

1. To what extent does language affect a de facto precedent in CJEU judgments?
2. What is the perception of ‘precedent’ in CJEU judgments at the national level?

To investigate those research questions, an interdisciplinary mixed-methods approach was taken. First, systematic literature reviews were carried out, focusing on theories of ‘precedent’ in common law and civil law jurisdictions; elements of legal precedent and of the concept of precedent outside of the legal arena; the role and form of de facto precedents in CJEU judgments. Those literature reviews informed the research design for in-depth interviews with various actors at the CJEU and national member state judges, as well as corpus linguistic analysis of judgments themselves.

Analysis of the various data collected has demonstrated that language does indeed play an important role in the development of a de facto precedent in CJEU judgments. Indeed, that data





“Over the past 15-20 years, the development of a *de facto* precedent in European Union (EU) law has been the subject of significant academic debate, centring around questions of what it means for a supreme court to ‘make law’ and when it is possible to say that its decisions are ‘precedents’.”

shows that the notion of ‘precedent’ in any court is the product not only of a conscious jurisprudential strategy but is also produced by the mechanics of jurisprudential drafting. While those two elements exist in any court, the multilingual nature of the judgments of the CJEU introduces another variable. CJEU judgments are collegiate documents, drafted in French (the working language of that Court) by jurists whose mother tongue is generally not that language. The pleadings, observations and other documents which inform those judgments undergo many permutations of translation into and out of up to 24 different languages, and the ‘authentic’ versions of those judgments, as presented to the outside world, are for the most part translations<sup>2</sup>. Thus, to understand any type of *de facto* precedent in CJEU judgments, one must take account of elements such as: the approximation inherent in

translation; how consistently formulaic techniques in the drafting language (which go to the development of ‘precedent’) can be carried over to translated versions; and how to ensure the uniform reception of CJEU judgments across 28 Member States.

More information about this data analysis and the LLECJ Project in general, including papers and other project outputs, can be found on the project [website](#). This article series will continue in the next issue of Open Access Government, which will focus on the LLECJ Project’s third sub-project: the linguistic aspect of the role of Advocate General at the CJEU.

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UNIVERSITY OF  
BIRMINGHAM

**Karen McAuliffe**  
Reader in Law and Birmingham Fellow  
School of Law, University of Birmingham  
Tel: +44 (0)121 414 7269  
[k.mcauliffe@bham.ac.uk](mailto:k.mcauliffe@bham.ac.uk)  
[www.karenmcauliffe.com](http://www.karenmcauliffe.com)  
[www.twitter.com/dr\\_KMcA](https://twitter.com/dr_KMcA)

# Portugal in the limelight of companies looking to expand in the EU region

Companies are continuing to expand into Portugal and the country is reaping the economic benefits of the added exposure, Bernardo Trindade, President of the Executive Committee of Portugal IN explores

**T**ech start-ups and digital development centres are being set up all over Portugal and hiring qualified local workers. Google has opened a support centre creating 500 tech jobs for skilled workers, as well as BMW, Daimler, Volkswagen, BNP Paribas, Natixis, Zalando, Bosch and Siemens, Euronext, Revolut, among many others.

**“Looking at the big picture regarding investment in Portugal, investors are expressing a growing optimism on the country attractiveness with the majority confident it will continue to improve over the next three years, exceeding those of Germany, the UK or France...”**

Expatriates working in these companies are finding a welcoming country with high-quality standards of life. Being a tolerant, open and safe society help it rank the fourth most peaceful in the world. Its privileged hours of daily sunlight, leisure offer, gastronomy, affordability, and healthcare system, contribute to make it the favourite European country for expats to live, and where they find the highest personal happiness. English is widely spoken in business, resulting in being easy to find multinational operations with Portuguese, Spanish, British and German people where English is used as the main language.

The UK investors also recognised this opportunity and are contributing to the momentum. The UK in 2018 climbed to the top position on Portugal source of foreign direct investment – ahead of China, Netherlands and Spain – with an investment flow of £711 million (€896 million), a growth of 18% vs. the previous year. FDI from the UK in 2018 represents almost a quarter of total inward investment to Portugal.

That’s why that in the loom of Brexit, the Portuguese



Bernardo Trindade

Government is committed to maintaining its ancient preferential status for Britain and its citizens, pillared from the world’s oldest active alliance, established in the Anglo-Portuguese treaty of 1373.

In April 2017, the Government of Portugal launched a temporary taskforce – Portugal IN, aimed at assisting UK businesses to integrate seamlessly in the country for operating their EU bases, in joint work with the Portuguese Trade and Investment Agency, Turismo de Portugal and other public entities. A total of 22 companies from the UK invested in Portugal in the last two years creating more than 1400 jobs, according to FDI Intelligence, a Financial Times service.

Portugal IN task force foresees to work with British businesses and promote Portugal as an ideal destination for investors seeking to remain in the EU. The country offers exceptional guarantees to residents including a friendly tax environment, a modern infrastructure, security, political and economic stability, a comprehensive health system, and access to highly qualified and innovative talent at a competitive labour cost, with the added benefits of staying in the EU and under the same time zone as the UK.

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With Portugal and Britain economically interlocked, the Government of Portugal has developed a series of contingency plans for all Brexit scenarios, in order to minimise economic disruptions. Since 2017, the Government has been engaging with the major economic and trade sectors from Portugal that rely on the UK, with specific measures around technical and financial support developed, ready to be deployed to minimise the impact of Brexit on the economy, including a dedicated front office desk to assist UK companies wishing to relocate or branch to Portugal.

With the UK as the largest source of tourists to Portugal, the country also seeks to maintain a smooth and stable process for British visitors, with guarantees of visa exemption, dedicated passport control lanes, possible mutual recognition of driving licenses and access to the Portuguese health service.

Along with the same spirit, Portugal recently launched the [#Brelcome](#) campaign to reaffirm the country's

ongoing commitment to British citizens, with the slogan “Portugal will never leave you”. In one month, the campaign reached already more than 13 million people in the UK.

Looking at the big picture regarding investment in Portugal, investors are expressing a growing optimism on the country attractiveness with the majority confident it will continue to improve over the next three years, exceeding those of Germany, the UK or France, according to the most recent European survey by EY, a consultant company. This is a clear signal for investors to include the country in their shortlist for potential investment locations. ■

**Bernardo Trindade**  
**President of the Executive Committee**

Portugal IN  
Tel: +351 213 221 200  
[geral@portugalin.gov.pt](mailto:geral@portugalin.gov.pt)  
[www.portugalin.gov.pt](http://www.portugalin.gov.pt)



# Consumer confidence in the safety of products

Graham Russell, Chief Executive of the Office for Product Safety and Standards, explains why consumer confidence in the safety of products is at the core of what the organisation does

Consumer confidence in the safety of products is at the core of what the Office for Product Safety and Standards (OPSS) does. Right from the start (the Office was set up in January 2018), ministers wanted the Office to make its presence felt, so the past year or so has been about delivering results while building national capacity for product safety.

The Office's work is evidence-based. In August 2018, OPSS published the UK's first national product safety strategy – 'Strengthening National Capacity for Product Safety' – along with the Strategic Research Programme, to produce high quality strategic science-based research to strengthen the evidence base for the development of product regulation policy, delivery and enforcement.

The strategy document was a major milestone and underpins the Office's aim to support frontline regulatory officers and step in where its expertise and national reach are required – for instance, the ongoing concerns over Whirlpool tumble-dryers.

Practical measures taken by the Office include developing the Code of Practice: Supporting Better Product Recalls (PAS 7100) with BSI, the UK's national standards body and making it and other robust standards freely available to Trading Standards officers.

The Code, which also covers other corrective actions, is designed to help businesses plan in advance to deal with any potential product safety issue that might arise with products they have placed on the market or distributed. OPSS has trained 300 trading standards officers on implementing the Code and held regional workshops for business.

OPSS is also working with Trading Standards at key entry points to strengthen the UK's ability to stop unsafe

products at the border and has made an additional investment to support local authority led teams at points of entry in the UK, through National Trading Standards.

In product safety terms, the landscape has changed considerably with a profusion of products, innovative and diverse means of manufacturing them and new ways of selling them to the public. Again, confidence for consumers and businesses is a central theme.

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**"The Industrial Strategy states that: "All businesses choosing to set up a Primary Authority partnership will have access to assured advice, with support from Growth Hubs". OPSS is currently working on pilots with Growth Hubs to make this a reality and is supporting Local Enterprise Partnerships in translating and coordinating regulatory frameworks that focus on local business needs, simplifying the way regulation is delivered."**

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The same technological developments driving these changes can be harnessed to enhance protections, for instance, internet-enabled products to alert householders and manufacturers when there is a potential fault.

Good intelligence is essential and the OPSS Intelligence unit shares data and intelligence with partners, including local authority trading standards, National Trading Standards, Citizens Advice and the Intellectual Property Office. OPSS is also commissioning research into consumer behaviour to support evidence-based policy and help get more people to register their products to make them easier to recall.

More widely, the Office's Local Regulatory Delivery team is busy driving Better Business for All, which brings together businesses and regulators, creating



partnerships to identify issues facing local businesses and find ways to support them. Technical support for regulators goes hand in hand with supporting businesses to comply – and when the two are working together the results are likely to be better.

The Office has been building its scientific and technical expertise and resources and its NMO Technical Services facilities in Teddington play a significant role in conformity assessment – an important way to support confidence in goods and services i.e. by providing assurance to consumers that their products or services meet specified requirements. It can also help businesses to compete where conformity assessment and accreditation are required.

This work supports the UK Government's Industrial Strategy which seeks to ensure that regulation is as simple as possible for businesses. That means supporting businesses to comply with regulation at a local level. One of the most important frameworks for this is Primary Authority, administered by OPSS, which enables businesses to receive assured advice from a single local authority, which other regulators must consider.

The Industrial Strategy states that: "All businesses choosing to set up a Primary Authority partnership will

have access to assured advice, with support from Growth Hubs". OPSS is currently working on pilots with Growth Hubs to make this a reality and is supporting Local Enterprise Partnerships in translating and coordinating regulatory frameworks that focus on local business needs, simplifying the way regulation is delivered.

The UK Government's top priority is to keep people safe and Britain's product safety requirements are among the highest in the world. At the start, I said consumer confidence in the safety of products is at the core of what OPSS does and we see the purpose of all our work as protecting people. ■

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**Graham Russell**  
**Chief Executive Officer**

Office for Product Safety and Standards (OPSS)  
Department for Business, Energy and Industrial Strategy (BEIS)  
[opss.enquiries@beis.gov.uk](mailto:opss.enquiries@beis.gov.uk)  
[www.gov.uk/government/organisations/  
office-for-productsafety-and-standards](http://www.gov.uk/government/organisations/office-for-productsafety-and-standards)  
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# Wider Public Sector Legal Services (RM3788)

Mark Jones, Commercial Agreements Manager – Legal Services at Crown Commercial Service discusses the Wider Public Sector Legal Services (RM3788)

All organisations benefit from being able to manage their risk and avoid costs – the wider public sector is no different and providing a framework for appropriate legal services in this field is potentially complicated.

Crown Commercial Service's (CCS) Wider Public Sector Legal Services panel was launched at the end of 2018, but its story began long before that.

To ensure we got it right for all potential wider public sector users across the UK, we needed to listen and learn well before the design stage.

Only by approaching the task in this open manner could we confidently provide a Wider Public Sector Legal Services panel which successfully ensures a minimum level of quality and a maximum price for services tendered.

The panel's launch provided an ideal opportunity for us to address a gap in our coverage following the expiry of our old Legal Services Framework.

CCS's renewal programme to replace that framework comprises three separate panels for central government and other specified bodies, all developed in conjunction with the Government Legal Department, as well as this fourth panel for the wider public sector.

The Wider Public Sector Legal Services panel is more customer focussed and commercially attractive than its predecessor.

We prepared extensively during the design process for the new panel: consulting with the market through Prior Information Notices (PINs), workshops, briefing sessions and a short Request for Information (RFI) process. It's so

important to listen to customers and suppliers at this stage of the process because it not only pays dividends at the end – it makes the resulting agreement so much more user-friendly and successful.

This engagement with groups of potential wider public sector users really did help us to understand their priorities, the way they were currently using legal services and the key specialisms they required support from.

The outcome of that process was true clarity – in order to work effectively, our new panel would need to be designed in a very different way than we might otherwise have realised.

We looked at all the evidence we had generated and opted to break the panel into lots and sub-lots that would provide for sectors, geography and the UK's three legal jurisdictions.

The resulting lots were regional service provision, property and construction, rail transport and separate full-service firm lots for England & Wales, Scotland and Northern Ireland. We also tailored the legal specialisms available via the panel based on user feedback. Therefore, we've enabled wide-ranging specialisms, such as licensing, education, social housing and primary care law to suit various parts of the wider public sector, such as local authorities, educational authorities, housing associations and NHS trusts.

We've placed 71 suppliers on the Wider Public Sector Legal Services panel and almost one-third of them are small and medium-sized providers. We enabled suppliers to compete for a place on Lot 1 (Regional Service Provision) provided they had the capability in a minimum of one specialism and one region, thus, opening up the panel to regional and specialist firms. This approach





ensures customers can access a broad variety of organisations no matter where in the UK legal support is required.

We at CCS feel the main benefits of this panel are the ease of call-off it can offer customers, with options for further competition and direct award where needed. We also hope our customers will find value in the maximum tendered hourly and daily rates and other extras, such as two hours initial free consultation.

It is in ways like this we hope the panel's built-in, value for money ethos shines through.

The Wider Public Sector Legal Services panel provides consistency and reassurance to customers by placing a maximum on chargeable rates. For example, if a public sector organisation opts not to run a further competition, but to award directly, they can be assured those rates will still have been completed through the panel.

Our legal services team remain focused on improving the panel further and are currently in the process of digitising the filtering and selection processes on it for even greater ease of use.

Just like any other organisation, those in the wider public sector sometimes require legal support and they should be entitled to effective and value for money options. We feel this panel provides just that.

For more information on The Wider Public Sector Legal Services panel please visit the CCS webpage [here](#). ■

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**Mark Jones**  
**CCS Commercial Agreements Manager – Legal Services**

Crown Commercial Service

Tel: +44 (0)0345 410 2222

[info@crownccommercial.gov.uk](mailto:info@crownccommercial.gov.uk)

[www.crownccommercial.gov.uk/agreements/RM3788](http://www.crownccommercial.gov.uk/agreements/RM3788)

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# Development sites and why you should pay them a proper visit

Anthony van Hoffen, Real Estate Partner at Lewis Silkin LLP, provides us with a guide discussing what you need to check when making development site visits

**R**egeneration projects and new developments are a big commitment and the development sites as part of these projects have a tendency to throw up 'interesting issues' with almost infinite variety. It might be bats, or slow worms. It could be an adjoining owner having annexed what they considered to be no man's land. Maybe it's an old oil barrel full of 'something green'. Our standing advice is to 'expect the unexpected'.

If spotted early enough these issues often stay just that – 'interesting issues' that can easily be dealt with. If spotted too late, however, they can cause anything from a mild headache to a very expensive disaster.

Parties should always carefully inspect any site they propose to develop. This should always occur before they exchange to buy the land – after that point it's usually too late to pull out or re-negotiate the price. An interesting issue spotted before you have exchanged contracts is usually someone else's problem to resolve. An interesting issue spotted after you exchange contracts is almost always all yours.

So, in addition to our possibly unhelpful advice of expecting the unexpected, our more practical advice is always, without fail, rain or shine, come what may, carefully inspect the site.

We have set out below a checklist of the sorts of things (in no order of pri-

ority) that you should have in mind on every site visit, regardless of the site's location, size or nature. When attending a site, we would suggest you take with you the following so that you can keep checking what the site actually looks like compared to what you think that the site should look like:

- A colour copy of the Land Registry title plan; and
- A copy of the development proposals (or at least an idea of what these are – e.g. location of buildings, size and height of buildings, etc.).

Whilst we hope that the following suggestions are helpful, the list is not exhaustive and clearly every site will have its own particular issues. Additionally, one would hope that some of the following matters will also be covered through other lines of enquiry, survey and/or legal searches usually undertaken – but they should still be considered on a site visit.

- Access to the site – both during and after the development phase. Look at the extent of roads/adopted highway/pavements
- No-entry signs, bus stops (or even post boxes)
- Access across the site – is there any evidence of existing or past, private or public rights of way or common areas? Look for gates, holes in

fences, worn patches in grass, play areas

- Are there any possible rights of light issues? Look for windows or other openings overlooking the site or evidence that there was recently a building on adjoining land that might have had windows overlooking the site
- Services crossing the site. Do any pipes or cables cross over or under the site? Is there any evidence of a septic tank and, if so, what is the route of the drainage pipe? Look for manhole covers, junction boxes and electricity substations on or near to the site
- What do the boundaries look like (on site and compared with legal boundaries shown at the Land Registry)? Are they clearly identifiable? Are there any party walls?
- Is there any evidence of telecommunications apparatus (e.g. on roofs or buildings especially)?
- Is there any evidence of or potential for species? For example, is there a pond with signs of wildlife? Could there be bats on site?
- Are there any signs of Japanese knotweed or other invasive species such as Himalayan balsam?
- If there are trees on site, consider whether any tree preservation orders might exist



“If spotted early enough these issues often stay just that – ‘interesting issues’ that can easily be dealt with. If spotted too late, however, they can cause anything from a mild headache to a very expensive disaster.”

- Where any existing structure is to remain in situ, are there any possible ‘overhang issues’? Look for balconies or other parts of an existing structure that jut out over public footpaths or highways
- Are there any structures or areas of land which could be operated by third parties, e.g. advertising hoardings, car-parks, substations, etc?
- Is there evidence of anyone in actual occupation (e.g. short-term tenants) or people using the site for any purpose (e.g. storage)?
- Is there any rubbish or are there any other matters which need to be cleared prior to the vendor giving vacant possession?
- Is the site vulnerable to squatting – should measures be taken to secure the site in this regard, and by whom?
- Is there any evidence of (potential sources of) contamination? For example, manhole covers that may lead to underground containers, or stains on the ground from oil or other substances

- Is there any evidence of formal action being taken against the property, either by the local authority or otherwise (e.g. by way of signs affixed to boundary structures, etc)?
- Is there any evidence of any ongoing disputes or matters likely to give rise to a dispute?
- What adjoins the site – railways, canals/underground waterways, etc? Might they impact during or after the development phase?
- Is the site made up of unusual gradients or is there any evidence of tunnels, ventilation ducts, etc?

As a development progresses different issues may ‘transpire’ at different stages. We would, therefore, suggest that you revisit the checklist on more than one occasion during the course of each project to ensure that there have not been any unexpected developments.

In addition to development work, Lewis Silkin can advise on all real estate legal matters including real estate litigation, and construction.

Lewis Silkin can also support your legal needs for commercial contracts, advertising and marketing, intellectual property, data protection, defamation, corporate and tax, litigation, employment and immigration.

Lewis Silkin is a legal provider for the Crown Commercial Service RM3788 Wider Public Sector Legal Services for Lot 1 Regional Service Provision.



## LEWIS SILKIN

**Anthony van Hoffen**  
**Partner – Real Estate**

Lewis Silkin LLP

Tel: +44 (0)207 074 8358


[Anthony.VanHoffen@lewissilkin.com](mailto:Anthony.VanHoffen@lewissilkin.com)

[www.lewissilkin.com](http://www.lewissilkin.com)

[www.twitter.com/LewisSilkin](https://twitter.com/LewisSilkin)



# The Tip of the Iceberg – but what lies beneath?



**NFI 2016-2018 report confirmed £4.3m in 'Error payments' made to Suppliers (£4.5m – previous period), out of £275m in overall errors identified. Does this make sense?**

**Government has concluded that the potential range for likely losses in unmeasured areas of government spend ranges from £1.96bn to £19.6bn, or 0.5% to 5.0% of public services expenditure.**

*(source: Cross-Government Fraud Landscape Annual Report 2018, published by the Cabinet Office)*

**What proportion of potential errors relate to Spend with Suppliers (Trade Creditors)?**

**With £100m's being identified and recovered in error payments to Suppliers within the Private Sector, why would the Public Sector be any different?**

**Is it time to find out what lies beneath...**



## Twice2much Supplier Health Check

Our reviews enable Clients to benefit from a detailed forensic review of their Accounts Payable transactions bespoke to their own organisation.

To draw an analogy with our own Health, we would compare our reviews to an MRI/scan approach rather than a GP check-up. The depth of our reviews enables the identification of errors previously unknown to the organisation.

### STAGE 1 - Identification/detection

- Access to £100,000's of technology, analytics and resources
- Access to dedicated experienced professionals
- Provides multiple-layer interrogation of transactions with Suppliers
- Specialist expertise in reviewing Supplier transactions and identifying anomalies



### STAGE 2 - Verification/validation

- Expert detailed analysis of transactions at individual Supplier level to validate and investigate anomalies
- Obtaining evidence to support initial findings



### STAGE 3 - Recovery/Reporting

- We supply the system, processes and resources to recover the errors found on our Clients' behalf
- Flexible but targeted reporting provides significant additional benefits to Clients



Our Supplier Health Checks are carried out on a **NO RECOVERY - NO FEE** basis enabling Clients to benefit from a **FREE Health Check** if no errors are found.

# Government: Dealing with resource challenges by infusing flexible procurement capability

Claire Foxall, Executive Vice President, Public Sector of Proxima reveals that when faced with peaks in demand, government is increasingly dealing with resource challenges by infusing flexible procurement capability

**M**odern commercial functions need a range of procurement capabilities and their requirements continuously evolve in skillset and capacity. Proxima can provide access to the high quality, experienced and flexible procurement capability that will enable you to deliver quickly, across a broad range of priorities.

## Government's commercial challenges – our observations

Central Government spends £49 billion each year on external contracts that are often complex and demanding, representing a vast array of important (and often life-enhancing or life-saving) goods and services.

New service models emerge, driven by changes in technology, lessons in what works and rising public expectations. These may require collaboration between multiple public organisations and significant commercial input. When commercial staff with the right skills are involved at the right time and in the right way, they make a massive difference to the quality of the services and projects delivered by government.

At a time like this, there has never been a greater need for highly skilled and effective commercial staff who

are able to develop contracting arrangements in a complex and changing environment, under the weight of constant public scrutiny.

Because the needs of procurement are project-driven and the workload profile is inherently 'peaky', it makes the supply of commercial staff difficult to plan. Furthermore, there is a lack of the right procurement skillsets available to offer support at the right time. As a result, the public purse and quality of procurement outcome suffers.

This staffing challenge is highlighted by the Cabinet Office who state that their top three priorities for their Commercial Capability Programme in 2019 are:

1. Services/products – Focus on the service(s)/product(s) Commercial Capability Programme team delivers ensuring that we reach as many Civil Servants as possible to help upskill both their commercial and contract management capability.
2. Customers – Becoming more customer focused to ensure a delivery orientated approach.
3. People – Getting the right people into the right roles, with the right skills.

The Cabinet Office 2019 Commercial Capability Programme top priorities are:

- Services/products;
- Customers;
- People.

## Proxima working with government: The right commercial capability at the right time

Proxima's 'Capability on Demand' service provides access to a range of skills, capabilities and resources from Proxima's award-winning and end-to-end procurement services function. Support ranges from director level through to operational support, across a broad range of categories and procurement and commercial disciplines. This enables commercial functions to boost internal teams by topping-up on capacity and capability when and where needed.

## Create best-of-breed procurement in your organisation

The simple On-Demand framework sets out how to work together, either time and materials, project or programme based. Once established, Proxima will simply provide the agreed capacity and capability to assignments as required, enabling



## Proxima on procurement: Ensuring that commercial functions are fit for the future

Proxima works with clients to optimise how they buy and what they buy, ensuring that commercial functions are fit for the future, that each pound spent is productive and delivers value for money. Working with numerous clients across the public and private sectors, they are a knowledge aggregator, focused solely on procurement. Supporting customers by delivering this knowledge to them through an innovative, practitioner-led model, helping them to become smarter in the long-term and deliver value faster in the short-term.

Proxima is the UK's biggest procurement consultancy and proudly a UK SME, with numerous category, commercial and operation specialists working around the UK and globally, helping some of the most recognisable businesses and government departments to become better at what they do.

To find out how we can develop your commercial ambitions, visit [www.proximagroup.com](http://www.proximagroup.com) or contact Claire Foxall, Executive Vice President Public Sector, on [claire.foxall@proximagroup.com](mailto:claire.foxall@proximagroup.com) or +44(0)7503 165637.

your department to have complete flexibility in the capability they choose to buy-in, allowing commercial leaders to solve a variety of challenges. Typical engagements focus on:

- On-site, off-site, or hybrid sourcing teams;
- Specific programme or project support;
- Contract or pipeline assessments;
- Resource backfill, or pre-hire capacity;
- Part-time or leveraged roles;
- Operational support.

### Benefits of our Capability-on-Demand service

**Focus on core:** Invest in core needs using external capability to deliver projects, surge and provide hard to find skills.

**Speed up:** Shorten recruitment cycles with immediate and flexible access to specialist and tactical procurement capacity.

**Embrace agility:** Embrace new knowledge and skills through "on the job" training and post assignment knowledge transfer.

**Gain insights:** from other organisations and commercial functions bringing a different perspective to your team.

### How it works in practice

Each assignment is scoped and agreed prior to commencing service delivery, with a plan and target outcomes. The assignment may be standard or bespoke in nature including:

- 'Bitesize' versions of other Proxima Services;
- Resource augmentation to cover surge, backfill or provide specialist capability;
- End-to-end project or programme delivery, start quickly and without complexity.

Simply funnel requests to Proxima and your resource can be live in days...

**Engage:** Start a conversation with Proxima. We will explain all our services and how to engage us.

**Agree:** Simple and compliant contracting (e.g. MCF2, Call-Off, Direct Award or other).

## Getting started quickly and without complexity in a compliant manner

Proxima uses a flexible resource model to maximise productivity; specialists, generalists and operations are all in the mix, meaning that departments can benefit from exceptional and efficient On-Demand procurement support without the fixed investment.

Through working with many of the world's leading commercial functions to deliver better procurement, Proxima can give constant insights into different sectors, supply markets and effective working practices.

They then use this knowledge in an innovative delivery model which aligns capability and capacity with their client's needs whether they are strategic or more tactical in nature.

**"Proxima's Capability on Demand provided us with flexible experienced resource where and when we needed it."**

*Commercial Director, Central Government Department.*



**Claire Foxall**  
**Executive Vice President, Public Sector**  
 Proxima  
 Tel: +44 (0)20 3465 4500  
[Claire.foxall@proximagroup.com](mailto:Claire.foxall@proximagroup.com)  
[www.proximagroup.com](http://www.proximagroup.com)  
[www.twitter.com/Proxima\\_Group](https://twitter.com/Proxima_Group)

# Smarter working: Improving employees' performance

Dr Shahnaz Hamid, Programme Leader at [InterActive Pro](#) and [Edology.com](#), tells us how smarter working improves employees' performance

The massive growth of technology and globalisation processes have led businesses to break borders and find new ways of improving their employees' performance. In this context, the concept of "smarter working" has been developed as a response to recent changes in work processes and employer expectations in relation to outcomes and productivity. Although organisations have only started to implement the principles of smarter working, this approach can be considered an effective way of improving employee engagement, motivation, performance and productivity at both individual and organisational levels.

## What is smarter working?

Smarter working is a complex approach of managing individuals' work by offering them more flexibility, autonomy and means for collaboration through the innovative use of information and communication technology. At the organisational level, smarter working can be regarded as a managerial strategy to establish effective work processes and communication between employees.

Thus, the key features of this approach are the provision of a level of flexibility depending on the productivity or specific needs of employees, less dependence on workplace and office areas and the active use of technology to promote communication and collaboration. Consequently, the application of the principles of smarter working in an organisation leads to arranging offices according to employees' needs to provide them with opportunities for working alone or in a team, as well as using flexible working hours and remote work options.

Smarter working is associated with organising employees' work in a way that most suits their own needs and capacities. While being provided with opportunities to

choose flexible working hours and the place to work, an employee can decide what schedule to follow and whether to work in an office or from home in order to be more creative and productive. The result of this approach is the increase in employees' autonomy, enthusiasm, productivity and engagement.

Smarter working can be applied by managers to improve performance, but this may require some changes to their corporate culture. This approach is more suitable for organisations that follow a people-centred culture, are agile and can easily create dynamic teams of empowered employees. This way, employees with different work styles can utilise their potential and successfully contribute and collaborate to achieve individual and organisational goals.

## Recommendations for achieving smarter working

To achieve the principle of smarter working for improving employee performance, follow these recommendations:

Managers should change their focus from evaluating work through "presence or absence at the workplace" to evaluating the outcomes. Therefore, employees should be allowed to select the number of working hours and the place of work depending on their goals and deadlines.

It is necessary to share schedules of all employees and provide proper channels for contacting one another. Collaboration is an important component of smarter working and should be facilitated despite the presence or absence of employees within a single office.

Organisations must guarantee the availability of suitable technology to conduct virtual meetings and enhance online communication. Access to electronic documenta-



tion and other tools should be provided to all employees and they should not be limited in this area.

If the employees are working from the office, they should not be limited to assigned workspaces for completing their tasks and should be allowed to use other spaces as well. It is good to be aware of the specific conditions that make the employee more productive and motivated, including preferences to work in quiet spaces, at the office or at home.

Managers can determine peak hours of productivity for every employee in order to set a schedule that will contribute to enhancing their performance. This way each employee will be able to reach their highest level of productivity and achieve the desired goals.

### **Enhancing organisational performance through smarter working**

If employees work at convenient locations and choose appropriate working hours, they will certainly become more focused, stimulated and motivated to achieve their goals. As a result, their performance improves and distractions and mistakes are greatly eliminated. Technology has contributed to making cooperation and communication simpler and dynamic, so team members across borders are able to communicate and work

effectively. Therefore, it is possible to save on valuable resources, decrease costs and steer employee energy in the right direction to achieve organisational goals.

Organisations should appreciate the fact that smarter working is associated with more flexibility, independence and freedom for employees to become more responsible and deliver the desired outcomes. This approach leads employees to be better motivated to become more productive. Smarter working is being actively applied in modern organisations to recognise employee needs, address their talents and improve their productivity. The realisation of this principle is associated with accepting the presence of various work styles that should be taken into account while managing employees. ■

**Dr Shahnaz Hamid**  
**Programme Leader**

*Interactive Pro and Edology.com*  
[www.interactivepro.org.uk](http://www.interactivepro.org.uk)



# Is Smart Working contributing to employee unhappiness?

According to a [survey by the Personal Group](#), there has been a 20% drop in workplace happiness over the past three years. Alison White, at PLACEmaking discusses if Smart Working has contributed to this

The percentage of people who are happy most of the time at work has reduced year on year from 51% in 2017 to 43% in 2018, and now only 41% in 2019. Many report being so dissatisfied that they struggle to get out of bed to go to work, and 79% percent of those surveyed can't recall anything from the last month that has made them feel positive about their working life. Meanwhile, the [2019 Deloitte Millennial Survey](#) has revealed that young people are becoming increasingly disillusioned about work, sceptical of business motives, and pessimistic about economic and social progress.

Should we be surprised? Well a traditional argument is that even before getting to work, the commute for many is often ridiculously expensive and thoroughly exhausting, while [the office that awaits](#) them at the other end is frequently a dull, characterless place reflecting the uninspiring culture of the employing organisation, and the technology solutions and support on offer are at best functional.

Yet the alarming speed at which levels of workplace happiness are dropping in fact coincides with rapid change in the way we work through growing adoption of [Smart Working](#) over the last five years. The question is, therefore, does Smart Working actively

contribute to employee unhappiness and dissatisfaction?

Recent fundamental changes in work styles and patterns have emerged and been enabled through the wider distribution of mobile technologies and remote access to digitally stored information. These advancements have facilitated a demand for more flexible working arrangements and adaptable contracts that reflect personal ambitions or family responsibilities.

The impact of these changes on the traditional office is such that organisations of all sizes have had to recognise that demand for space has changed and its utilisation has steadily reduced. Smart business leaders have understood that they were paying for space and services despite shrinking headcounts and changing work styles – space could often be unoccupied for up to 60% of the core working week. As a result organisations have sought to reduce their operating costs, and property overheads have been high on their agenda – along with the introduction of Smart Working.

A key benefit of Smart Working is driving better use of space and technology – an important requirement for these aforementioned forward-thinking leaders. However, the essential driving component behind Smart

Working is people. Whilst you could hire a contractor to tick the initial boxes by redesigning your office space and enhancing your technology provision, the desired performance of these changes is dependent on people who, on the whole, don't passively just do what is demanded of them.

And that is because, while it's easy to accept that the way we work is changing, the reasons for why we work are as complex as they always were. Aside from the money we need to earn for our basic survival, there are many other reasons why we go to work that are all-too-frequently ignored in the rush to implement Smart Working. Yet conversely the success of its implementation depends emphatically on people accepting change.

If we consider the non-financial reasons of going to work then we might understand why some people seem to mourn the loss of the daily commute and a rigid 9 to 5 structure to their working day. Social interaction, companionship, performance comparison, mentoring, counselling, career planning, peer to peer learning, personal technological development or even the simple feeling that we are part of something bigger... these are all frequently quoted as valuable benefits we derive from going to



work. And for those of us with caring responsibilities, physically leaving our domestic life or chores behind just for a few short hours is often quoted as a primary motivation for going to work.

The messaging that accompanies Smart Working often downplays these benefits, and the simplistic language used can be rigidly imposing, implying that large amounts of time must be spent working away from the office and when back in there is the need to hunt out a desk because everyone is now desk sharing. However well-intentioned such messaging might be, it directly challenges the non-financial benefits that people want from their workplace experiences

So should we stop Smart Working?

No. The Smart Working genie is truly out of the bottle. What we need to do

is recognise that we are in a transitional period – from the traditional ways of working that were embedded in our workplace culture for many years to a new and quickly evolving way of working. We have to acknowledge that place is still hugely important, and that whilst we can no longer afford to maintain large volumes of under-utilised property, what we can afford needs to represent more than just a shrunk-down version of a traditional office.

We are social creatures at heart, and working from home only suits us for part of the time. When we want the additional benefits of stimulating company, learning from others, the use of exceptional technology and the buzz of social interaction, we need to be in a modern and adaptable workplace that is designed to facilitate these very things - not simply a super-

ficial and generic place to do 'work'.

*Find out how PLACEmaking can help you to successfully implement Smart Working in your organisation. Get in touch at [placemaking.co.uk](http://placemaking.co.uk) or email us at [info@placemaking.co.uk](mailto:info@placemaking.co.uk).*

## PLACEmaking

**Alison White**  
**Co-Founder**

PLACEmaking

[www.placemaking.co.uk](http://www.placemaking.co.uk)

[www.twitter.com/placemaking\\_uk](https://www.twitter.com/placemaking_uk)

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# How GDS is transforming services and building digital capability across the public sector

Kevin Cunningham, Director General of the Government Digital Service (GDS) explains how the organisation is transforming services and building digital capability across the public sector in the UK

**G**DS has achieved a lot since it was created in 2011. Among our successes, we often (and rightly) talk about the creation of GOV.UK which saves the government £63 million a year, our spend controls process which saved £1.2 billion and the creation of our common components.

But I'd like to share some of our most recent achievements, which show that seven years on, we are still leading the digital transformation of government. In particular, how the [GDS Academy](#) is providing benefit across the public sector.

## Digital transformation across the public sector

To achieve digital transformation at scale, there must be collaboration across the public sector. As the leader of digital transformation in government, GDS has an important role to play in helping create the right environment that allows organisations across the sector to transform.

In May, we published our updated [Service Standard](#) which service teams use to create and run great user-focused public services. It is now written with a wider audience in mind, after initially being aimed at central government.

We've also encouraged collaboration by launching the [Local Digital Declaration](#), with the Ministry of Housing, Communities and Local Government. This set of guiding principles helps support local authorities to deliver user-centred digital services and platforms. Since its publication in July, more than 150 organisations have signed the declaration.

For GDS to remain a leader in digital transformation, we must stay at the forefront of emerging technologies. This will make our work sustainable for future users of our tools and services. One example of us using new technology and future-proofing our work is through making GOV.UK readable to voice assistants. It is now possible to find more than 12,000 pieces of government content through your smart speaker, including when the next bank holiday is and how to get free childcare.

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**“Our digitally capable workforce will continue to grow. Currently, we have 17,000 digital, data and technology specialists in government. With our 10,000 GDS Academy graduates, we are well placed to deliver the strategy’s ambition of having one of the most digitally-skilled groups of public servants in the world by 2020.”**

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However, we want to make sure we're using this new technology in the right way to solve the right problems. This is why we've recently published the [Government Technology Innovation Strategy](#).

We know there's lots of great work happening with emerging technologies across government from our [Technology Innovation in Government Survey](#), which was published last year. We've used these findings and conversations with academics and industry and public sector employees experts in roundtable discussions from Shoreditch to Edinburgh, to feed into the strategy.

## The GDS Academy

The GDS Academy has been one of our most successful ways of building technical capability across the public sector and it continues to grow.





**Kevin Cunnington**

Set up five years ago in a room above a jobcentre in Fulham, its original aim was purely to develop in-house capability at the Department for Work and Pensions. Since then, the academy is now open to all civil servants, local government employees, devolved administrations and other public servants to provide the skills needed to transform public services. And, we have expanded to four permanent locations across England: London, Leeds, Manchester and Newcastle – as well as running pop-up academies in Newport and Birmingham.

We reached an exciting milestone in March this year when we celebrated having trained 10,000 people. And, as our numbers have grown, so has our curriculum. We offer courses for non-specialists, such as our popular [Digital and agile foundation course](#), alongside further development and leadership training.

Emerging technologies also feature on the courses. In March, we launched an '[Introduction to artificial intelligence in government](#)' course' and last October, we began running [GDS Academy masterclasses](#). In these seminars, world-leading academics and industry experts share their expertise on how new technologies are impacting public services.

Our success has been noticed and emulated abroad. We inspired Canada to set up their own academy and went over to Ottawa to share our knowledge. We also work closely with the [Scottish Digital Academy](#) and helped them when they were setting up.

### **Continuing to lead**

All of this work helps us to deliver on the priorities of the [Government Transformation Strategy 2017 to 2020](#). However, digital transformation will not stop in 2020. We will build on these successes and strong foundations and keep innovating to bring new technologies to make government work better for everyone.

Our digitally capable workforce will continue to grow. Currently, we have 17,000 digital, data and technology specialists in government. With our 10,000 GDS Academy graduates, we are well placed to deliver the strategy's ambition of having one of the most digitally-skilled groups of public servants in the world by 2020.

To help us achieve this goal come join us for a GDS Academy masterclass, attend a course or suggest a new pop-up academy location.

Through all our hard work and our efforts in building digital capability across the public sector, I am certain we will remain one of the world leaders in digital government. ■

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### **Kevin Cunnington Director General**

Government Digital Service (GDS)

[www.gov.uk/government/organisations/government-digital-service](http://www.gov.uk/government/organisations/government-digital-service)

[www.twitter.com/gdsteam](https://twitter.com/gdsteam)

# Digitally Transformed™

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At Visionist we know that your Digital Transformation investments must deliver substantial realisable benefits.

Our approach to digital transformation has allowed the department to realise the invest to save benefits of replacing their expensive legacy IT infrastructure with a Digitally Transformed IT service.

This has enabled the department to migrate from legacy PSN services to cloud based commodity services, within 6 months, enabling true business transformation opportunities.

**But technology is not enough on its own.**

Our passionate and energised enthusiasts have proven methods with demonstrable experience in delivery of tangible outcomes based transformation, in highly complex public sector environments.

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To digitally transform your organisation let's talk

**T:** +44 (0)20 3883 8201

**W:** [www.visionist.com](http://www.visionist.com)

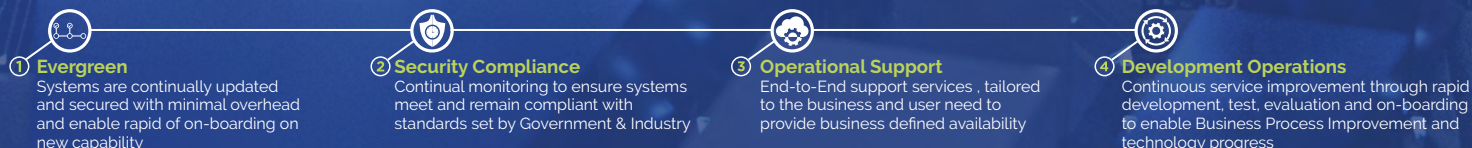




## The steps to becoming Digitally Transformed™



## Beyond Transformation



## Digital Transformation in action

### The Challenge

The Department needed to ensure minimal business disruption whilst ensuring that the disparate legacy systems and local "solutions" that had become the mainstay of Departmental Business would not hamper the desire to create a Digitally Transformed™ organisation. In addition, the Department had key Information Services delivered and hosted on the Public Services Network (PSN) where the Network itself was a secured "Official" environment.

Visionist were able to grasp the scale, scope and complexity of the challenges the Department faced, and deployed its resources, to support the IT Department as they led their community through change at pace, in an organised and prioritised fashion.

### The Solution

Initially, Visionist designed the road-maps through acceptance, technical debt, inherited backlog and beyond. Thereafter, we embedded high performing agile teams, working in collaboration with Civil-Servants to ensure effective skills and knowledge transfer, helping them transition from using out-dated technologies and methodologies to a future-proofed department, using an aggregation of loosely coupled Cloud Technologies and an agreed Reference Architecture.

Our implementation of a demand management process via a prioritised pipeline, coupled with a strong customer focused Service Management function ensured that IT resources worked on activities that maximised business impact. Our strategy and technical-innovation enabled the Department to move its operational, data and digital-streams to cloud-hosted solutions, reducing legacy services and the reliance on disparate data centres and internal infrastructure.

Our ability to choose the right technologies to cut complexity and add agility, enabled the use of core services such as identity management and web security, which could readily be hosted on Amazon Web Services (AWS) and Microsoft Azure, utilising a model that secures the endpoints rather than the bearer network, in order to maintain and comply with security protocols. This strategy enabled the department to migrate at pace to Office 365

The Department's reliance on PSN applications was recognised and had the potential to be a barrier to the transformation. Our highly skilled technicians and architects innovated to develop a solution which provided PSN access via a standard Internet secured connection (accredited for OFFICIAL). This innovative "Reach-Back" solution enabled the Department to migrate from its legacy services to a new cloud-based service in their required timelines, with the ability to access PSN-hosted applications, whilst maintaining security governance and protocols.

Throughout, Visionist produced transition strategies based on an agreed reference architecture. To further ensure all systems decisions were in-line with Business Need and overseen by a newly instated Technical Design Authority, ensuring architectural consistency and re-use. This enabled our technical architects to make informed system decisions covering all areas of the transformation.

### The Benefits

Utilising incremental prioritised deliverables, we were able to focus on high value business needs, enabling the successful delivery of 14000+ end-user-devices, enabling major cultural and behavioural change, significantly reducing outdated technology whilst transforming the data and information solutions available to all staff. In summary Visionist has enabled the Department to:

- Manage all devices effectively with a high degree of security assurance
- Use modern collaborative ways of working
- Implement a mobile first unified communications strategy

- Utilise a seamless reach-back to PSN Legacy applications
- Improve service performance
- Increase user satisfaction
- Exploit Evergreen technology with iterative improvements
- Enable cultural and behavioral change
- Create a Dev Ops capability to incrementally implement Business Process Improvements

### The Outcome

We have enabled the Department to move its operational, data and digital streams to cloud-hosted solutions, reducing legacy services and the reliance on disparate data-centres and internal infrastructure/servers.

The re-use and simplification have allowed more agility and speed around delivery as well as the following savings:

- Retired PSN circuits - £440k per annum
- Third-party PSN hosting for PSN Apps - £50k per annum
- FCOS Hosting and Decommissioning - £1M per annum
- Move to Unified Communication and the Augmentation of Contracts £1.25M per annum
- Internal support of solution and removal of SI requirement circa £5m per annum

In conclusion our Reference Architecture and associated Roadmaps ensured applications and data were migrated with little or no down-time, there-after greatly improving the customer experience, e.g. failed logon attempts down by 15-20%.

Furthermore, our expertise has enabled us to architect highly scalable and re-usable solutions which could be used across government to improve user experiences and dramatically reduce costs.



# The challenge of maintaining an up-to-date well-patched end-user device environment

Maintaining an up-to-date well-patched end-user device environment has been a challenge for many organisations, but with a modern approach, it does not need to be, Sam Newman, Technical Director of OGEL IT LTD explains how

Companies are becoming increasingly concerned about the threats to the security of their data assets and are looking for help in ensuring they have taken appropriate steps to mitigate the risks. Some organisations are hesitant to patch or upgrade their systems, as they are so worried about the potential operational impact that they end up not doing it at all.

**“We work with our customers to design an autonomous patching cycle for their Windows estate that works for them by maximising exposure to early release issues and minimising the potential impact on business operations.”**

You may have heard the term Evergreen IT, if you haven't, it's been around for several years and the term is used to capture an approach to the provision of loosely coupled services that are designed to always be up to date. In the past, IT services have been engineered around a stack of software with several layers of integration resulting in an unnecessarily complex solution that can make it difficult to update or costly to replace certain elements. Adopting a stack of loosely coupled services counters this by using software and services that are self-contained and accessible via



standard interfaces, such as web browsers to minimise or remove the requirement for complex integration and simplifying the move to an alternate product.

The move to modern cloud services that are updated and maintained by established organisations largely removes the decision to upgrade out of the consumers' hands, which can be worrying but helps ensure exposure to new vulnerabilities are minimised across back end systems. This, however, does not resolve the same issue with the client operating systems and associated software packages as these are not typically treated as self-contained and have dependencies across multiple systems.

Windows 10 and Office 365 click to run goes a long way to extending this evergreen IT model out to the desktop and with the right implementation and operational procedures, can create a secure and easily maintained environment. Microsoft Office 365 delivers several well-known services via both a browser and through the client installed applications and handles all the back-end management of Exchange, SharePoint and file services and so customers don't have to. Windows 10 and the office client are designed to be automatically updated on a regular basis and will adopt this approach by default.

Embracing the automatic updates is critical for ensuring the most recent



vulnerabilities are addressed, therefore, keeping organisational assets secure. There are many ways to manage the release effectively to minimise the risk of an update negatively impacting the business operation and this is all about preparing for the updates and identifying problems early. Creating a phased release strategy with key system owners early in the release scheduled helps move the testing burden from IT teams to the business reducing overheads and having suitable processes in place to capture and report issues early is critical.

OGEL IT has transitioned several customers to Window 10 and Office 365 helping them to embrace the 'Ever-green IT' strategy, resulting in a significant increase in the update compliance of their end-user devices estate and a reduction in the overhead on operational teams to patch and maintain the environment. We work with our customers to design an autonomous patching cycle for their Windows estate that works for them by maximising

exposure to early release issues and minimising the potential impact on business operations.

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**"Embracing the automatic updates is critical for ensuring the most recent vulnerabilities are addressed, therefore, keeping organisational assets secure."**

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We encourage our customers who have previously outsourced the management of their end-user estate to external providers to take a more active role in the management of their devices which improves the quality of the service to the end-users and reduces costs. Where organisations don't have the capability in-house, we work with them to help build it up by providing a flexible support service that can adapt over time as the internal capability grows or where they just don't have the headcount or desire to take on the management we have done that for them.

Our entire team started their careers in IT support and have been in receipt

of poorly designed solutions and services that don't consider the associated operational overheads and, therefore, everything we design and deliver takes this into account and we take great pride in the quality solutions and services we deliver to our customers.

If you would like to find out more about what we do and how we can help you then please get in touch via email, phone or our website.



**Sam Newman**  
**Technical Director**  
OGEL IT LTD  
Tel: +44 (0)1438 567 551  
[www.ogelit.com](http://www.ogelit.com)





# What are the data protection challenges of using AI in healthcare?

This article considers the increasing political interest in the use of Artificial Intelligence (AI) in healthcare and considers how data protection legislation may help to build greater understanding and trust

**A**rtificial Intelligence (AI), machine learning, deep learning, neural networks – call it what you like, there's a lot of excitement about the ability of software to analyse masses of data, spot patterns, learn (sometimes independently) and to make conclusions and produce insights that are entirely new.

It is not unusual in the world of new technologies for this level of excitement and chatter. What is new though, is the political and legislative interest in this technology, which distinguishes it and its potential to re-shape our world. This is especially so in the case of healthcare.

In May 2018, the Government allocated millions of pounds for the NHS to use AI in the early diagnoses of cancer and chronic disease. Then in October 2018, the newly appointed Health and Social Care Secretary Matt Hancock brought renewed focus on the use of AI with his *'The Future of Healthcare'* document, which will enable access to real-time data and set standards for security and interoperability.

Most recently (June 2019), Simon Stephens, Chief Executive of the NHS said: "We are seeing an artificial intelligence revolution that will be a big part of our future over the next five

years, with technologies that can cut the time patients wait for scan results and ease the burden on hard-working staff. We're therefore kicking off a global 'call for evidence' for NHS staff and technology innovators to come forward with their best ideas for how we should adjust our financial frameworks to best incentivise the use of safe and evidence-based AI and machine learning technologies across the NHS."

My observation is that the technology needed in healthcare is not the clever, cutting-edge stuff. It's the basic ability to access a patient's record electronically, send emails rather than faxes,



book appointments, automate rotas and surgery schedules and locate equipment digitally within a hospital. Investing in the basics would bring efficiencies, savings and better patient experience.

However, there is, of course, a place for the cutting-edge of technology, which is capable of transformative change, rather than incremental efficiency. The challenge in healthcare is that the professionals who will use the technology will need to trust that it works and will indeed reduce the burdens on them.

That word, trust, sums up the most significant barrier to the adoption of AI in a healthcare setting. Patients do not know if they can trust new software, when no-one can explain in layman's terms how it works. Doctors do not know which of the many applications out there have been properly coded or calibrated, with physician input and based on accurate data.

The House of Lords Select Committee on AI recently identified 'transparency' and 'explainability' as key requirements if AI is to become an integral and trusted tool in our society.

So that's the political landscape. What about the legislative perspective?

The General Data Protection Regulation 2016 ("GDPR") already has transparency and accountability at its core. The regulators identified that if people do not trust organisations with their data, they will not want to share it or allow access to it. In turn, that will stifle innovation and prevent organisations delivering better, more tailored services – such as personalised medicines. GDPR aims to increase transparency to foster trust so that data is properly protected and han-

dled through a range of measures. In addition to the well-established requirement for physical and technical security, these measures include:

- Privacy notices that provide greater clarity about what data is collected, how it will be used and for what purpose. This is not without its challenges in the use of AI systems: How can you easily explain complex software; How do you let people know what data you hold when the AI could produce new data; how can you explain how data will be used when the AI could produce insights which were not expected/predicted?
- Greater rights for individuals to control how their data is used including rights to have data deleted and ported
- Data protection impact assessments to ensure that the use of any new technology will be GDPR compliant
- Privacy by design so that the protection of privacy is built into the design of any new system rather than being a retro-fitted after-thought.

GDPR also anticipates particular types of processing which AI will use, known as "profiling": this means automated processing of data to evaluate, analyse or predict aspects of the individual, including their health. This type of analysis of a collection of factors about a patient to assist with diagnosis will be used by some AI in a healthcare context. Profiling is permitted, provided that it is properly explained in privacy notices including the 'logic' involved and the significance and consequences of the profiling.

Clearly then, AI in a black box will not comply with GDPR as well as appearing unfriendly to healthcare professionals

who want to be able to follow the machine's logic and check the result(s) it has provided. Profiling has the potential for the AI to make automatic decisions such as giving a diagnosis and whether or not to treat a patient. Used in this way, profiling can only be carried out if either the individual has consented, or the processing is necessary for the purpose of a contract between the patient and clinician/organisation, or is permitted by law.

Organisations, therefore, need to carefully analyse whether their use of AI amounts to 'profiling' and whether there is an 'automatic' decision made as a result. Where a human reviews results of an AI's analysis or recommendation, this is not an 'automatic' decision but it will of course be important for the human to be able to decide whether or not they agree with the AI.

GDPR is designed to accommodate new technologies such as AI – indeed the measures described above should help to facilitate greater transparency and understanding of how AI works and therefore to ensure that it is trusted by all who use it.

[www.gowlingwlg.com](http://www.gowlingwlg.com)



**Jocelyn Paulley**

**Partner**

Gowling WLG

Tel: +44 (0)203 636 7889

[Jocelyn.Paulley@gowlingwlg.com](mailto:Jocelyn.Paulley@gowlingwlg.com)

[www.gowlingwlg.com](http://www.gowlingwlg.com)

[www.twitter.com/JossDoesIT](https://twitter.com/JossDoesIT)

# Placecube's Digital Place: Building an ecosystem of digital services

Dr. Gavin Beckett, Executive Director of Placecube, discusses his vision on building an ecosystem of digital services based on common service patterns

In my career to date, leading digital for Bristol City Council, and then working with the Ministry of Housing, Communities and Local Government (MHCLG) Local Digital Declaration team, several things have become clear to me.

- Our services and the whole business model of local government need to be designed afresh, based on an understanding of user need, if we are to adapt successfully to continued austerity and the impacts of Brexit – the new normal.
- There has been good work by a small number of leading councils, tackling a small number of the many things councils do. But it's been limited to those councils and has cost them a lot of money and time.
- As a sector we cannot afford for every council to spend the budget and elapsed time to design every one of their services from scratch. It just won't happen... too many councils will fall off the financial cliff edge before they get very far.
- The answer cannot be for the majority of councils to remain trapped in their current forms with their current IT and digital products and services. Nor can it be for one single system to replace the hundreds in use across the UK – there is no political or commercial support for a single Local GDS, GOV.UK or the equivalent of the ill-fated NHS National Programme for IT.

## So, what can we do?

Working with the MHCLG Local Digital team last year I was privileged to be part of the collective drafting and publication of [the Local Digital Declaration](#). I support the intent behind it – when a service is designed in the internet age, the user research, interaction and content design/service patterns, data structures, API and integration definitions should all be published openly so that they can be implemented by other councils and by suppliers who want to support this good practice.

Once there is a recognised pattern and model for implementation of the digitally enabled service that meets user needs, councils should expect their suppliers to offer products built on those patterns – and not to extract a premium for it!

Re-use will lead to reduced costs for a better outcome, and if councils across the country can adopt them easily and cost-effectively, it will contribute to a massive reduction in cost across the sector.

The great digitally enabled services that were built by suppliers with councils like Bristol, Hackney, Camden, Stockport and Southwark are largely based on open source code which in many cases has been published openly on GitHub.

But it's not easy to pick them up and place them down into another council

with different technical infrastructure and back-end systems. We need to pay attention to the standards needed to wrap these systems in a way that makes them interoperable and portable, with clean boundaries and well-defined services and interfaces.

If we can define a set of ecosystem standards that enable multiple building blocks to be used together in a way that ensures they will fit – like Lego™ – we will move further towards the vision of [local government as a platform](#) that people like me, [Dave Briggs](#) and [Mark Thompson](#) have been writing about for the last few years.

That's the vision we have at Placecube – we want to create that ecosystem based on open standards, where we can provide a re-usable set of building blocks “Cubes” based on the work we've done with [Bristol](#) and [Camden](#), for other councils to adopt easily and cost-effectively.

But unlike many of the legacy suppliers in the local government market, we don't want to lock customers in and push you to buy everything from us – we want to be able to easily incorporate the best digital services from other suppliers, who have already understood user needs, worked to design services and then realised them with new code.

We invite them to work with us on the common standards needed to ensure



Dr Gavin Beckett

services can be composed together by councils who want to re-use the great work that has already been done. And whilst councils are the democratic centre of the local place, we know that people, businesses and visitors to the area interact with hundreds of other organisations that provide services, advocacy or information advice and guidance.

Our vision of an open ecosystem is more than just councils being able to use better digital services, it is to digitally connect the network of organisations in a place, enabling them to provide or access data, services and to collaborate on meeting community, individual and local business needs.

For further information take a look at the Place Designs already being used to run leading UK local public services at [www.placecube.com](http://www.placecube.com).



**PLACECUBE**

**Dr Gavin Beckett**  
**Executive Director,**  
**Product Research & Innovation**

Placecube

Tel: +44 (0)20 8895 6756

[enquiries@placecube.com](mailto:enquiries@placecube.com)

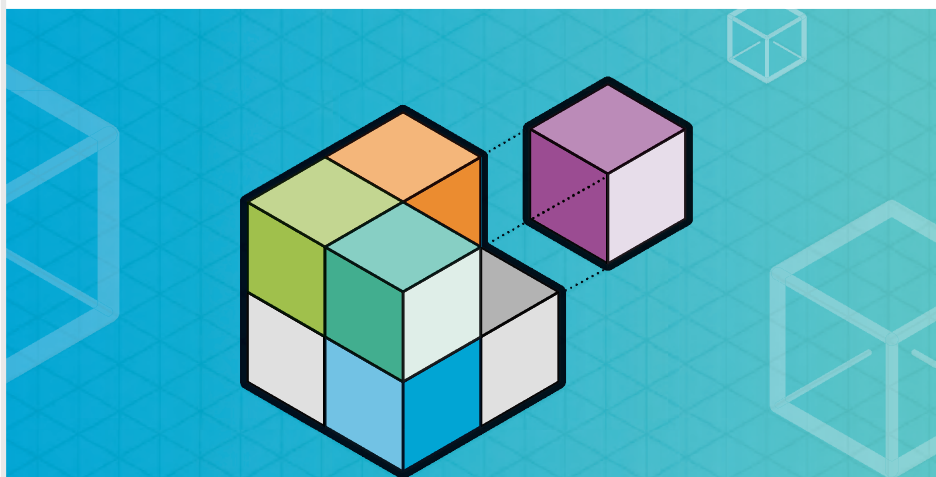
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# Finding a dividend for transformation

Rob Fotheringham, Managing Director, highlights the work conducted at Fotheringham Associates to help businesses develop a successful digital transformation strategy

**W**e all know local government are under huge pressures to maintain and improve services with diminished resources and that all are now looking towards digital transformation as a way to achieve this goal and ultimately save money.

However, effective digital transformation is a costly and long-term undertaking and is not simply the creation of a digital veneer over the existing services. To truly transform it requires the redesign of both the end to end process and the user experience to provide a seamless fulfilment of a customer request so that it passes through the organisation without friction and duplication of effort.

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**“We urge you to look again at your project portfolio and consider whether the investment you are making can be used to really contribute towards a broader strategic ambition.”**

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The good news is that with a slightly different mindset you can turn all of your ICT projects into enablers of transformation. Our view is that even the most unexciting projects can provide a way of contributing to both the cost and delivery of the transformation and we believe that every opportunity must be seized to push things along.

At Fotheringham Associates, we work with the public and third sector organisations to help understand and unlock

their business, technology and internal capabilities to meet the challenges of digital transformation. This is an example from one of our projects.

## **An example**

General Data Protection Regulation (GDPR) compliance was for many organisations a typical regulatory project; a large investment in time and money just to become compliant whilst standing still with no additional benefits. The standard approach is to minimise the cost and do as little as possible to make the grade.

However, one of our clients were different. When we were asked to help a London Borough with defining the approach for their GDPR project we were pleasantly surprised by their attitude. They wanted to know how they could use the opportunity to better enable the use of the information that they had across the council, with their sights on transformation. With limited documented corporate knowledge of their information assets there was a need to look at the whole council. The regulations expect organisations to understand in depth how their information is used and managed so it was clear that we they would need to examine business processes to develop the understanding required.

We devised an approach that would put their investment to work not just to move them towards compliance but also to provide insight into the

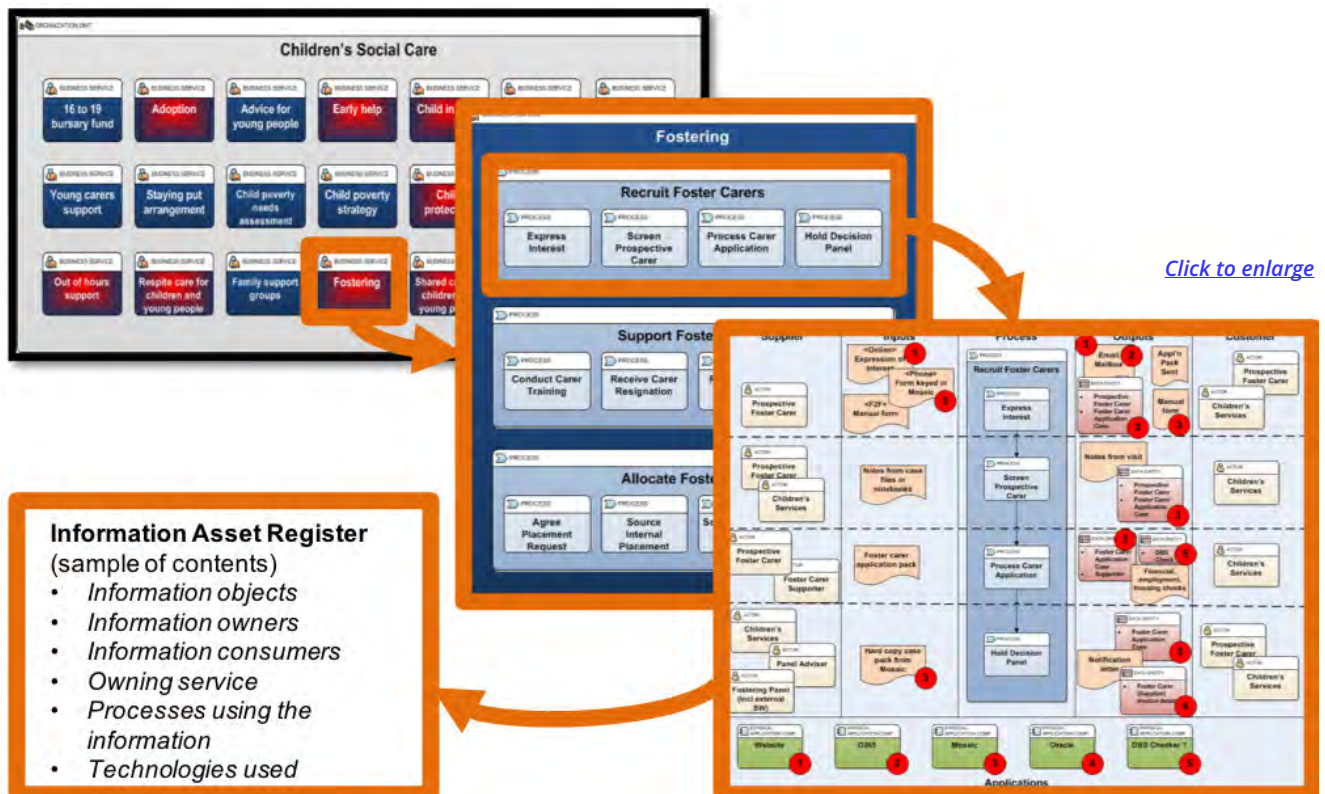
information assets they hold and how they relate to the council's operating model and structure.

By using a number of business architecture techniques, we developed a model of the services delivered by the council and collected them together into a series of functions (or capabilities). These functions could then be placed within the Council's structure which provided a holistic view of 'what' the council does and the key responsibilities of the directorates.

High-level processes that deliver the services were identified by engaging with service owners, which provided another layer to the business architecture. To drill down into each process, we used a SIPOC based approach, but at an architectural level of detail. A SIPOC is a tabular documenting technique for business processes capturing suppliers, inputs, process, outputs and customers and is more typically used in a Lean and Six Sigma context.

Each process was explored to capture who is involved, information flows and technology usage and documented in the SIPOC. These were then assessed to identify the information assets to populate the Information Asset Register that formed a key input for the risk assessment part of the GDPR project.

The graphic below illustrates how the resulting outputs can be used, the example shows how it is possible to



drill down from the children social care services, via the fostering service to the high-level process that recruits foster carers and then into the flows within the lower level processes.

## The dividend

The model can be traversed to provide the knowledge required to deliver the council's Information Asset Register and provide a lens into the very heart of council services in a consistent and comprehensive way.

As you can see the legacy from this project not only includes the outline business architecture for the council as a whole, but the SIPOCs hold a wealth of information and already provide insight into where improvements can be made. During the creation of these it became apparent that there are areas of duplication, inefficiencies and instances where technologies available where not being used to their fullest extent. Reading across the model provides additional value.

For example, you can see which business processes each team is involved in, flows of work across departments, use of key information objects by different directorates, cases where multiple technologies are used for the same basic job and much more. It opens the door to a smörgåsbord of opportunities to transform and/or consolidate.

We would, therefore, argue that the architecture models created during this GDPR exercise provide a fantastic foundation for launching a meaningful digital transformation effort across the council. We urge you to look again at your project portfolio and consider whether the investment you are making can be used to really contribute towards a broader strategic ambition.

Having whetted your appetite, you will be delighted to hear that over the next four issues we will be taking you on a whistle stop tour of business and

enterprise architecture techniques to illustrate how they can enable the transformation of your business operation and your ICT landscape.



**Rob Fotheringham**  
**Managing Director**  
 Fotheringham Associates  
 Tel: +44 (0)780 966 8792  
 rob@fotheringhamassociates.co.uk  
 www.fotheringhamassociates.co.uk



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# IS SMART WORKING CONTRIBUTING TO RISING LEVELS OF EMPLOYEE UNHAPPINESS AND DISSATISFACTION?

According to a survey by the Personal Group, there has been a 20% drop in workplace happiness over the past three years.

[Click here to view our ebook.](#)





**IS SMART WORKING  
CONTRIBUTING TO RISING  
LEVELS OF EMPLOYEE  
UNHAPPINESS AND  
DISSATISFACTION?**

JUNE 2019

ALISON WHITE  
PLACEMAKING



# Redefining success and motivation

Offering flexi-time is not agile working. Individuals need to feel valued – and that demands a fundamentally different approach to employee empowerment and trust, explains Adam Kene, Managing Director at Kene Partners

Employee attraction and retention models within the financial services sector are outdated and irrelevant to the younger generation. Brands, however well-known, cannot promote their way to employee satisfaction. Offering flexi-time is not agile working. Individuals need to feel valued – and that demands a fundamentally different approach to employee empowerment and trust.

Attracting top talent is a priority for every financial services organisation, yet too many of the younger generation now face a compromise between realising personal ambition and meeting corporate goals. This is a generation that wants to feel part of something, to make a difference. They do not enjoy the ‘protection’ of the rigid, hierarchical corporate machine, but feel constricted, even lost, in an environment that fails to celebrate individuality, innovation and drive.

The endemic inability to create a motivated workforce is at the heart of the current merry-go-round of staff between companies every couple of years: with limited job satisfaction and enjoyment, individuals can only aim for the offer of promotion and salary boost. The resultant lack of commitment and motivation also has a negative impact on the quality of client services. Rather than focusing efforts on delivering the best outcome for the customer, individuals become caught up in internal power games in a bid to win promotion or bonus. The goals of business, clients and employees are fundamentally misaligned.

This model is broken. Change is required, change that extends beyond the sticking plaster of hot desking or break-out rooms. Adding flexible working models to a dated, hierarchical business model is not creating the truly agile working environment now required.

## Redefining agile working

At the heart of a successful, engaged and committed workforce is a sense of purpose and excitement – and that means empowering and trusting individuals to do the job, not micromanaging every minute of the day. Redefining agile working means moving away from the constraints of set working hours and holiday entitlement and enabling employees to manage their own time in line with specific targets.

If an individual wants to spend eight hours with a client, for example, to truly understand the opportunity for R&D tax credits and support that business' drive for innovation, that is fantastic. Drop the children at school every morning? Take every December off? Fine. Essentially, as long as an individual is on target throughout the year to meet specific goals, and following a company code of conduct, then how, where and when the job is done is their choice.

Supporting this truly agile working model with strong, transparent performance and conduct measures is, of course, important. If problems occur, it is essential to be able to step in quickly. It is also important to understand an individual's goals: not everyone is motivated by promotion. Success should not be defined by the speed with which an individual marches up the corporate ladder – that does not dovetail with a desire to achieve more for clients. Success in an agile working model is defined by matching individual and client goals, not those of hierarchy and speed of promotion.

To create an essential sense of employee purpose demands a company culture that is predicated not just on winning business but on helping UK companies to innovate and succeed globally. Reinforcing this with a trust-based working model and a business culture that actively encourages input from individuals at every level, through regular open debates, for example, fosters that indispensable feeling of employee value.

## Conclusion

Many firms have tinkered with the working environment in a bid to attract and retain staff. But adding remote and flexible working to the existing, micromanaged hierarchy makes no substantial difference to a generation of individuals who want to take control, to explore their entrepreneurial spirit within a corporate environment.

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**“At the heart of a successful, engaged and committed workforce is a sense of purpose and excitement – and that means empowering and trusting individuals to do the job, not micromanaging every minute of the day. Redefining agile working means moving away from the constraints of set working hours and holiday entitlement and enabling employees to manage their own time in line with specific targets.”**

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If the financial services industry is to truly meet the evolving needs of both clients and employees, it is time to shake off decades of entrenched behaviour. A redefined agile working model creates a positive working environment and employees that are loyal, passionate to drive business values, and deliver the highest value and productivity for clients. It also creates the ultimate knock-on effect of improved client engagement and retention. ■

**Adam Kene**  
**Managing Director**

Kene Partners  
[info@kene.partners](mailto:info@kene.partners)  
<https://kene.partners/>  
[www.twitter.com/KenePartners](https://www.twitter.com/KenePartners)



# Why we need Generation Agile

The Agile Business Consortium is calling for the inclusion of agility and agile skills in the education of everyone from primary school children, to working professionals

**W**e believe not just in the value of agile thinking, but its necessity for the challenges that the future will bring our businesses and societies. However, agile skills are not currently taught in our schools or workplace training as a standard practice.

The Agile Business Consortium is certain that soon:

- Individuals will need agile skills to compete in the job market
- Organisations will require agile-minded employees to compete in the world of business
- Educational institutions and teachers will be obliged to focus on teaching agile skills and mindsets to prepare our young people for life and work in a constantly shifting world

## The employment landscape is changing

The concept of a job for life is already a thing of the past. This is partly because individual roles are evolving, requiring different skills, and sometimes disappearing completely.

The whole employment environment is changing, due primarily to three key factors:

- **The changing nature of work<sup>1</sup>** – as distributed teams and asynchronous

working become commonplace, contracting is on the rise, and there is an increased need for specialist experts.

- **Faster technological change<sup>2</sup>** – technical education in schools is likely to become obsolete by the time the students of that subject enter the workforce, and today's technical professionals must be continually learning to keep up.
- **Disrupted industries<sup>3</sup>** – including communications (particularly due to the mainstreaming of Artificial intelligence (AI) technologies), finance (with crypto-currencies being just one instance), and manufacturing (which is ever-more reliant on robotics), as well as many other examples.

With this massive and ongoing adjustment in employment, individuals need new skills in order to keep up.

## Future skills requirements

In 2018, The World Economic Forum looked at the top ten skills for jobs in that year and compared them with those that would be required by 2022.

The 2022 skills include a large proportion of specifically agile skills:

- Analytical thinking and innovation
- Active learning and learning

strategies

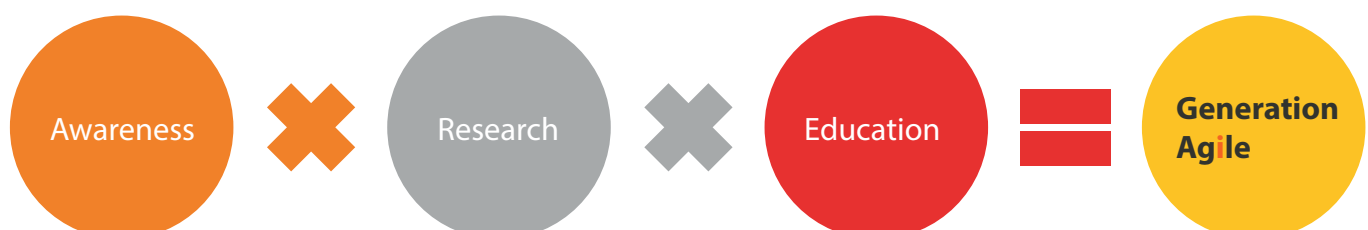
- Creativity, originality and initiative
- Technology design and programming
- Critical thinking and analysis
- Complex problem solving
- Leadership and social influence
- Emotional intelligence
- Reasoning, problem solving and ideation
- Systems analysis and ideation

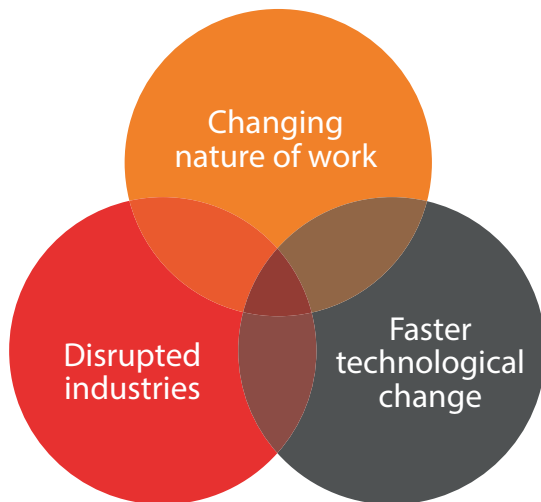
These are all skills that we need to see in almost all our employed talent – including those already in the workforce. However, that's not going to happen by itself, which is why educators and education policy makers are such an important part of this conversation.

The three factors influencing the employment landscape today (changing nature of work; disrupted industries; faster technological change), require these new agile skills. Skills like complex problem solving, creativity and innovation are what enable the changes that we are seeing, and are also the skills that will allow employees to succeed in that changed landscape. Those who do not gain at least some of these skills will fall by the wayside.

## A global issue

There is no geographic limitation on





the need for Generation Agile. America Succeeds stated in their Age of Agility report that 'without profound and rapid changes to how we educate our children, this nation faces the real possibility of falling behind countries with more nimble and innovative education systems'.

Chinese billionaire entrepreneur, Jack Ma of Alibaba, who is also an ex-teacher, emphasised the importance of skills-based education over knowledge-based education at the 2018 Davos summit, also adding that 'if we do not change the way we teach, 30 years from now we will be in trouble'.

In the foreword to 'Thriving in the New Work Order', Jan Owen, CEO of the Foundation for Young Australian's states: "By 2030, Australia's current primary school students will be close to finishing their school education and our high schoolers will be entering the workforce. To prepare them we must urgently invest in immersive, enterprise education and careers management strategies where the new 'work smart' skills are core to teaching, learning and assessment across all school and higher education systems". These studies and comments are reinforced by similar insights from all over the world.

## No time to waste

We must start now in order to benefit young people currently in secondary or further/higher education, as change will not happen overnight and many of them will be entering the workplace within the next three to five years.

We need to take an agile approach and make changes incrementally and embed them quickly. This will allow the rapid trialling of new practices, and for their benefits to be seen and shared straight away.

## What do we collectively need to do to create Generation Agile?

Firstly, we must build awareness of the need for Generation Agile amongst business leaders, politicians, educators and education policy makers, parents, teachers, today's employees and young people.

We also need research into how to create Generation Agile, answering questions such as:

- What skills should be taught?
- When should we teach them?
- How should they be taught?
- How does that fit into our school curricula?
- How should they be taught through workplace learning?

Then we can start changing the way that we, as a society, deliver education, through supporting educators, working with curriculum planners to discover future needs, and ensuring that those needs are acted upon quickly and effectively.

## You can help

Become a supporter of Generation Agile by joining the register of friends and sharing the supporters badge. Sign up at: [agilebusiness.org/generationagile](http://agilebusiness.org/generationagile)

To share an example of agility in education get in touch by email: [genagile@agilebusiness.org](mailto:genagile@agilebusiness.org)

Stay up to date by joining the Generation Agile mailing list at [agilebusiness.org/generationagile](http://agilebusiness.org/generationagile) and follow us on Twitter at @Agile\_Biz and #GenerationAgile

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## Tamsin Fox-Davies Head of Brand

Agile Business Consortium  
Tel: +44 (0)1233 228 882  
[tamsin@agilebusiness.org](mailto:tamsin@agilebusiness.org)  
[www.agilebusiness.org](http://www.agilebusiness.org)  
[www.twitter.com/Agile\\_Biz](https://twitter.com/Agile_Biz)

# How do we embed continuous improvement in our organisation?

CI and Quality Improvement are two tools for delivering efficient and effective public services. How can you embed these skills in your organisation? Andrew Sandford enlightens us here

**W**e work with many organisations implementing CI and quality improvement (QI) in their organisations. One of the drawbacks of trying to implement these is the lack of specialist skills in business analysis to deliver the improvement analysis.

By their very nature CI and QI are meant to be common repeatable processes used to continually analyse and improve your services. At their very essence they are not designed to be a one-off event done to services as part of projects.

With the progression of technology and other changes such as austerity budgets in the public sector the need for effective CI functions in organisations. CI based on lean thinking is an integral part of a best practice delivery pipeline including other approaches blended to deliver the best results (service design, lean start up and agile).

## What are the benefits?

There are many benefits to a true CI approach. Engaging all of the stakeholders in modelling and identifying improvements in processes will deliver process improvement. Engaging the stakeholders in the process ensures that people feel like they have contributed to the process and feel ownership/buy in to the changes, this also makes implementation easier.

With the people actually doing the

work being involved in designing the new processes you are getting better quality improvements and starting to embed CI thinking in your organisation. Given how far technology has moved in recent years and the lack of true CI happening in organisations there is process debt in almost all processes we encounter.

## What is process debt?

Many of you will have heard of technical debt in technology and software projects. Taken from Wikipedia – technical debt is a concept in software development that reflects the implied cost of additional rework caused by choosing an easy solution now instead of using a better approach that would take longer.

Technical debt builds up in software projects over time and unless addressed is likely to cause issues and sub optimal behaviour later in the life of your products/processes.

Process debt is a similar concept. Processes grow organically over time as additional checks and balances are added to processes as a result of changes, problems and issues encountered. For example, a change in legislation requires some new information to be collected or an issue happens in a process and new additional control/checking procedures are implemented to address the issue. Process debt is also caused by technology like when there is a software issue which will not be fixed

immediately and a work around is implemented on top of the initial process.

As problems occur and require urgent resolution often the fixes that are applied are not done by reviewing the end to end process merely as a 'sticking plaster' fix around the problem. These temporary solutions often become part of the normal ongoing process and are not removed when fixes are applied.

Do you have parts of your processes that we do because 'we have always done it that way'? If so, it is likely some of these things are part of your process debt. This process debt contributes to the user experience and hampers our ability to deliver the user or patient needs. As a result, our processes contain waste that adds cost and inefficiency.

## Why does this occur?

As already stated, time pressures and urgency affect the processes organic growth. A lack of skills, effective tools and time for our operational staff hamper their ability to deliver better change. Often only the people doing the work truly feel the impact of the process debt and understand the additional burden this puts on the delivery of services.

Instead of CI being applied to our processes instead improvement projects are instigated periodically where





experts from outside the service will look at delivering improvements with varying levels of engagement with the people doing the work. This can easily lead to a feeling that 'changes are being done to us' and lead to a lack of buy in, implementation problems and sub optimal changes. As a result, there are significant benefits that can be released by addressing process debt.

## So, what can we do about it?

Some of our most successful customers, getting the best results and true culture change are achieving this through embedding CI and QI skills and tools in their operational teams. These teams are delivering improvement as part of their normal day to day activities and are empowered to identify improvements.

It is a different model where small central improvement teams are operating as improvement coaches to the teams delivering services. Applying marginal gains thinking or the true Toyota Kata approach to embedding CI and changing the culture of the

organisation. An example is Edinburgh City Council where they have trained 200+ users in a year all supported by a small team of four improvement coaches.

We provide tools and training to help organisations to train their coaches and create sustainable ongoing improvement capabilities across the organisation. Our tools make the traditional process discovery/understanding much easier by providing tools that not only do it better but also save time for the analysts documenting the process.

The software takes the pain of process discovery away. Providing a platform where processes are capture live in workshops but also times and costs are embedded within the models meaning potential improvements can demonstrate not only a new process map but a model showing the benefits of the changes.

This is a true process improvement platform where maps are created and shared digitally and can be published

to a digital process handbook when changes are made acting as a single source of process information for compliance, information and to register further ideas for improvement.

If you need to improve processes or you map processes have a look at our blog [here](#) which shows how you can map and improve processes in an efficient and effective way.



## Andrew Sandford Director

We are Lean and Agile  
Tel: +44 (0)180 342 4050  
[sales@weareleanandagile.com](mailto:sales@weareleanandagile.com)  
[weareleanandagile.com](http://weareleanandagile.com)  
[@leanandagile](https://twitter.com/leanandagile)

# The consistent application of data protection rules throughout the EU

Andrea Jelinek, Chair of the European Data Protection Board spoke to Open Access Government about the consistent application of data protection rules throughout the European Union, including the use of personal data during election campaigns.

The European Data Protection Board (EDPB) is an independent European body, which contributes to the consistent application of data protection rules throughout the European Union (EU) and promotes cooperation between the EU's data protection authorities. Open Access Government enjoyed a conversation with Andrea Jelinek, Chair of the European Data Protection Board to find out more.

## Data protection rules throughout the EU/EEA

To kick things off, we ask Andrea to share her thoughts on the importance of consistent application of data protection rules throughout the EU/EEA, as well as promoting cooperation between the EU/EEA's data protection authorities. She underlines that one of the most important innovations of the General Data Protection Regulation (GDPR) is the new way in which the supervisory authorities of the European Economic Area (EEA) are closely cooperating to ensure the consistent application of data protection rules, as well as the consistent protection of individuals in the EEA. Andrea then develops this vital point in her own words.

"The consistent application of the GDPR ensures that all EEA data subjects can enjoy the same rights and can enjoy the same protection across the EEA. Liechtenstein, Iceland and Norway are also part of the EDPB and are members of the board but without voting rights, so there are 31 countries under the umbrella of the GDPR which include the current 28 EU Member States and the European Data Protection Supervisor (EDPS).

"In addition, harmonised data protection rules create a level playing field for businesses and organisations

both inside and outside the EEA. The goal of the GDPR is to have one set of rules that can be applied in a uniform way throughout the continent. I think it is really important not to have any more patchwork legal issues but just the GDPR. This is very important, on the one hand for the companies and on the other hand, for individuals. International companies, in particular, have a business advantage because there is one set of rules to follow."

## Personal data and EU legislation

The conversation then turns to reveal EDPB's recommendations for the European Commission when it comes to any issue related to the protection of personal data and new proposed legislation in the EU. Andrea explains that the EDPB can be requested to give advice to the European Commission and other EU institutions on data protection and stresses that all EU legislation should uphold the very highest of standards when it comes to data protection in line with the GDPR.

## The use of personal data during election campaigns

Andrea then explains her thoughts on the use of personal data during election campaigns and why she thinks that data processing techniques for political purposes can pose serious risks, not just with regard to the rights to privacy and data protection but also to the integrity of the democratic process. Concerning the EDPB's statement on the use of personal data in the course of political campaigns <sup>(1)</sup>, Andrea says that political parties and candidates are increasingly relying on data and sophisticated phishing techniques to monitor and target voters and European leaders, a point she goes on to develop.



“Some predictive tools are increasingly being used to find people’s personality traits, including political views and other personal categories of data. I think that this can be really scary, but your clicks on social media can be used to profile you, which allows companies to target you specifically to influence voting behaviour. As such, I think it is really important to monitor closely how personal data is used during election campaigns.

“The GDPR illustrates this really well in that the right for the protection of personal data could affect other fundamental rights, such as freedom of expression and the ability to think freely. Social media is important in the election process, but compliance is subject to supervision by independent data protection authorities. I think it is really important to have independent authorities. When the government notices that there may be problems around the use of personal data in political campaigning, they may ask an independent supervisory authority to look into this.”

### **Data protection: A call for global alignment**

In closing, Andrea says that following the implementation of the GDPR just over one year ago, it is really important to have a degree of global alignment regarding data protection and no necessarily to make a copy of the GDPR, but to concentrate on the core principles: “that is to be on the safe side regarding data protection worldwide,” she concludes. ■

1 [https://edpb.europa.eu/news/news/2019/european-data-protection-board-eighth-plenary-session\\_en](https://edpb.europa.eu/news/news/2019/european-data-protection-board-eighth-plenary-session_en)

**Andrea Jelinek**  
**Chair**

European Data Protection Board  
edpb@edpb.europa.eu  
[https://edpb.europa.eu/edpb\\_en](https://edpb.europa.eu/edpb_en)



# The challenges posed by officially published open data

In this article, I outline some challenges posed by officially published open data and explore the pragmatic approach of London-based technology company Doorda

I believe a tipping point has been reached and it is now essential for private and public organisations to capitalise on the tsunami of open data to provide improved products and services. Furthermore, organisations need to access “the whole wave”, not just a part of it. Ultimately, they need to mix it all in with their existing “lake” of data.

## Open data definition

Data is considered “open” if anyone is free to use, reuse and redistribute it – subject only to the requirement to attribute and/or share-alike. Most national governments are pushing the publication of open data, implemented on their behalf by official institutions, nationally and regionally.

Open data is usually information and statistics about the population, the areas where they live, the companies they work for and the things that affect their lives – transport, crime, health, trade, public sector expenditure, education, vehicles, weather, etc. The list grows daily.

Although open data is non-personal, completely avoiding privacy concerns such as GDPR, such data does present significant challenges.

## Open data challenges

Unfortunately, organisations rarely make use of this wealth of data because it is published in awkward,

inconsistent ways and often cannot easily be linked together.

Data is provided in various places and formats (national websites, regional databases, unstructured documents, semi-structured messages and structured records) and is accessible in various ways (on a webpage, from file transfer or programmatically).

Sometimes, data is published automatically to a location on the internet; sometimes it is made available on request; sometimes it is delivered by email. The frequency of publication varies according to the source of the data and can be any combination of decennial, annual, quarterly, monthly and daily. Publication can also be irregular, depending on human factors or events.

Since there are thousands of different organisations involved in the data collection and most of it is manually entered, the quality and consistency of this data is poor. Acme Widgets Limited in one town could be Acme Widgets (UK) in another, an instant data matching problem for anyone trying to automatically identify the property footprint of that company, along with any associated liabilities, licences or sanctions. Furthermore, this inability to reliably and consistently identify a property, area or company by an official unique identifier is problematic when trying to associate or

join open data to existing internal data.

Although open data almost always provides a latest or current view, many publishers do not provide a historical view, making it impossible, for example, to see data as it was on the day a decision was made or to see changes undergone over time. Implementing automated processes to provide history is complex and costly.

The publishing of open data by public sector organisations is not their primary focus, so data publication solutions are often fragile. Despite the efforts of the teams involved, “data outages” are common.

Multiple tools and strong technical expertise, not often available to those wishing to access and use the data, are often needed to exploit open data.

## Data uses

Yet there are rewards for those able to overcome the challenges.

Data scientists are keen to add new data to their predictive models for risk. Customer-facing organisations want frictionless web interfaces, automatically filling in the correct information to reduce keystrokes and accelerate sign-ups. For example, some websites use vehicle registration numbers to automatically and reliably fill out make and model. Many organisations want to analyse trends in



public sector expenditure. Marketeers are enriching in-house information with fresh data, improving their prospecting success rates.

## Further examples:

### Customer acquisition

Sophisticated customer segmentation to better identify target markets, improve marketing response models, refine risk assessments and provide speedy, frictionless on-boarding.

### Customer management

More complete customer models maximise potential revenue, assess risk events and optimise debt recoveries.

### Business planning

Broader, more complete data improves location planning, supplier assessment and competitive intelligence.

### Commercial finance

Proactively find potential funding needs and improve marketing responses and customer risk analysis.

### Commercial property

Improve location planning, win-rates for ratings appeals and investment analysis.

### M&A/Capital markets

Use a summary of trading premises, property assets, controlling parties, public sector contracts and receipts to inform conclusions and decisions.

## The best approach

I have worked with open data for many years now, researching, gathering, consolidating and linking thousands of Open Source datasets from official sources such as HMRC, Ordnance Survey, the Land Registry, local authorities and Companies House. I believe that capitalising on the value of this tsunami of data has three main themes:

### Business-ready data

The data must be made “business-ready”, allowing the experts to focus immediately on analysis and insight while avoiding the repeated delays, costs and risks of finding and preparing data. In fact, by harmonising data from multiple sources, it is possible to resolve many inconsistencies and errors, providing better data quality than from any single source.

There must be processes to identify and store changes in source data, building an up-to-date historical trail. Even if there are derived “scores” the untampered, detailed data must remain available, allowing analysts and data scientists to create their own unique insight and competitive advantage.

### Joined-up data

Where it makes sense, it must be possible to consistently and reliably join the open data from all these sources, to join the results to other

third-party data and to join with internal data held by the organisation. During harmonisation, certain key data elements should be identified, cleansed and standardised to allow joining – postal address, post code and company names.

Unlike legacy data matching solutions, this new data matching service must be automated, not require any human intervention and avoid “false positives”. The data matching service must remain available to cleanse and match other data sources when required.

## Self-service cloud platform

The data should be available on a “highly available” self-service cloud platform, with automated feeds keeping the data fresh and building a historical audit trail. Access to the data should remain simple, though, in bulk (extracted or queried) or by individual transaction via programmatic interfaces (SQL and API).

## Conclusion

Overcoming its challenges to capitalise on the value of Open Data avoids privacy concerns such as GDPR, however the value of open data for organisations is not found in isolated files, it is in consolidating all the relevant data into a single platform and providing easy, “joined up” access.



**Clifford McDowell**  
CEO

Doorda Ltd.  
Tel: +44 (0)800 133 7108  
clifford@doorda.com  
www.doorda.com

# Leading the “Digital Single Market” and fighting cybersecurity

Andrus Ansip, Vice-President of the European Commission in charge of Digital Single Market aims to lead the “Digital Single Market”, as this article explores, plus his priorities for fighting cybersecurity

**A**ndrus Ansip, Vice-President of the European Commission in charge of Digital Single Market has a number of responsibilities, including leading the project team “Digital Single Market” and fighting against cybercrime. So let’s look at these key areas now.

## Targeted investment and robust digital policies

In June 2019, the European Commission published the results of the 2019 Digital Economy and Society Index (DESI). This essentially tracks Europe’s overall digital performance and the progress of the European Union (EU) countries concerning their digital competitiveness. Certainly, countries with ambitious targets in line with the EU Digital Single Market Strategy who combined them with adapted investment performed better in a relatively short period of time. Having said that, the results showed that the largest EU economies are not front-runners when it comes to digital which suggests that the speed of digital transformation must accelerate for the EU to stay competitive at a global level.

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**“The EU and its Member States will work towards enhancing the level of security of digital processes, products and services. Within the G20 we can work towards the sharing of good practices in capacity building, a risk-based and multi-stakeholder approach.”**

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Vice-President Ansip, comments: “In late 2014, when we began drawing up a plan for the Digital Single Market we wanted to build a long-term strategy to stimulate Europe’s digital environment, minimise legal uncertainty and create fair conditions for everyone. Now that the EU has agreed on 28 out of 30 legislative proposals, creating 35 new digital rights and freedoms, the successful implementation of the Digital Single Market can significantly contribute to further improving country results. It is urgent to implement new rules

to boost connectivity, data economy and digital public services as well as help Member States to equip citizens with digital skills that are adapted to the modern labour market.”<sup>1</sup>

## Digital Single Market: World-class supercomputers

Supercomputers are a very important component in the development of artificial intelligence (AI) and they also boost Europe’s strengths in cybersecurity and blockchain, according to the European Commission. We know that AI can benefit many sectors, including healthcare, energy consumption, climate change and financial risk management. AI also helps to detect fraud and cybersecurity threats and enables law enforcement authorities to fight crime more efficiently.<sup>2</sup> In June this year, we learn that eight sites for supercomputing centres have been selected across the EU to host the first European supercomputers.

Commenting on this important development, Vice-President Ansip says: “These sites will give our researchers access to world-class supercomputers, a strategic resource for the future of European industry. They will be able to process their data inside the EU, not outside it. It is a major step forward for Europe to reach the next level of computing capacity; it will help us to advance in future-oriented technologies like the internet of things (IoT), artificial intelligence, robotics and data analytics.”<sup>3</sup>

## A call for stronger cybersecurity

Picking up on the aforementioned theme of cybersecurity, we know that in December 2018, the EU’s was agreed on and created a framework for certifying ICT products, services and processes that will be valid across the EU. In a speech by Vice-President Andrus Ansip at the Digital Day 2019 in early April 2019, he calls for: “Stronger cybersecurity” and “better protection





*Andrus Ansip, Vice-President of the EC in charge of Digital Single Market*

against online threats.” In this vein, he adds that: “This is the EU’s first internal market law that takes up the challenge of boosting security of connected products, IoT devices as well as critical infrastructure.”<sup>4</sup>

Digital security, amongst other areas, was placed under the spotlight during the occasion of the G20 Ministerial for Trade and the Digital Economy on 8th June 2019. Here, the EU and its Member States thanked Japan for its leadership in bringing forward discussions the most vital topics of the digital economy, including digital security, artificial intelligence (AI), as well as strategies to bridge emerging digital divides.

One thing the press release on this discusses is that the EU and its Member States are supporting Japan’s Data Free Flow with Trust initiative, which sets out to facilitate the cross-border flow of data: “among countries with high levels of privacy protection, data security and intellectual property rights.”

Another is that free, open and secure cyberspace is underpinned by the creation of a human-centred digital society, as detailed in the Paris call for trust and security in cyberspace. “The EU and its Member States will work towards enhancing the level of security of digital processes, products and services. Within the G20 we can

work towards the sharing of good practices in capacity building, a risk-based and multi-stakeholder approach.”<sup>5</sup>

### **Cybersecurity preparedness**

Finally, one noteworthy piece of news to briefly mention is that in early April 2019, the European Parliament, EU Member States, the European Commission and the EU Agency for Cybersecurity (ENISA) organised an exercise to test the EU’s response to and crisis plans for potential cybersecurity incidents affecting the elections in the EU.

Vice-President Ansip provides his thoughts on this which illustrate his key responsibilities around the “Digital Single Market” and fighting cybercrime.

“To secure our democratic processes from manipulation or malicious cyber activities by private interests or third countries, the European Commission proposed in September 2018 a set of actions. Together with the EU Member States and other EU Institutions we are implementing these actions. We also decided to test our cybersecurity vigilance and readiness towards secure, fair and free EU elections 2019 by organising the first in its kind EU exercise on elections. I believe that this is an important step forward for more resilient EU elections in a connected society.”<sup>6</sup> ■

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# Understanding and producing words with high-school maths

Professor R. Harald Baayen, Quantitative Linguistics, University of Tübingen, explains how we can understand and produce words with high-school maths

**L**inear Discriminative Learning (LDL) is a computational theory of how speakers produce and listeners understand words. LDL is developed with the aim of providing a functional characterisation of the cognitive skills that allow speakers to express their thoughts in words, and that allow listeners to decode the intended message from these words. In psychology and cognitive science, the organisation of words in standard dictionaries has long served as a model for the organisation of lexical knowledge in human cognition.

Accordingly, in comprehension a word's form has to be identified first. This form then provides access to the corresponding meaning. From a machine learning perspective, the first step is a straightforward classification task: Given an audio signal or a visual pattern, one specific entry in a fixed list of words has to be selected.

A fixed word list can be made to work for English, as this language makes use of a very limited set of inflectional variants (e.g., hand, hands; walk, walks, walked, walking). For richly inflecting languages such as Estonian, where nouns have no less than 14 case forms in the singular, and another 14 case forms in the plural, or Turkish, a language with verbs that have more than 400 inflectional variants, fixed word lists with millions of entries become computationally unattractive.

Fortunately, the task of word recognition can be reconceptualised as a multi-label classification problem. An Estonian genitive plural is no longer seen as an atomic entry to be discriminated from millions of other such atomic entries. Rather, the classifier now has to predict three labels, one for the content word, one for singular number, and one for genitive case. LDL goes one step further, and replaces these labels, mathematically equivalent to binary vectors with one bit on and all others off, by real-valued high-dimensional vectors extracted from text corpora, building on methods from computational semantics.

For the Estonian genitive plural of the noun for 'leg', the vector for 'leg', the vector for plurality, and the vector for the genitive, are summed to obtain the semantic vector for the inflected noun. LDL also represents words' forms by numeric vectors. In the simplest set-up, these numeric vectors specify which letter or phone n-grams are present in a word.

For written words, low-level visual features have been used successfully. For spoken word recognition, LDL employs binary-valued vectors coding for features that are inspired by the tonotopy of the basilar membrane in the cochlea. A given feature specifies, for a specific frequency band to which a section of the basilar membrane is tuned, the pattern of change in amplitude over time.

It turns out that, surprisingly, straightforward methods from linear algebra, basically the high school mathematics for solving a set of linear equations, suffice to map words' form vectors onto their corresponding semantic vectors (comprehension), and to map words' semantic vectors onto their form vectors (production), see Figure 1. When phone triplets are used to construct form vectors, model performance is excellent with accuracies for production and comprehension around 95% or higher across languages as diverse as English, Latin, Hebrew, Estonian, and Russian. When used to model speech production, the kind of errors typically observed in human speech are also made by the model. The model also successfully predicts a range of empirical findings concerning human lexical processing.

Although LDL is developed with the specific purpose of increasing our understanding of human language comprehension and speech production, it may have potential for practical applications. For instance, for speech processing, current deep learning systems heavily depend on surrounding words to guess which words are encoded in the speech signal.

Mozilla Deep Speech, a state-of-the-art speech recognition system that is trained on thousands of hours of speech, performs very well for running speech, but without context, its performance collapses. Tested on the

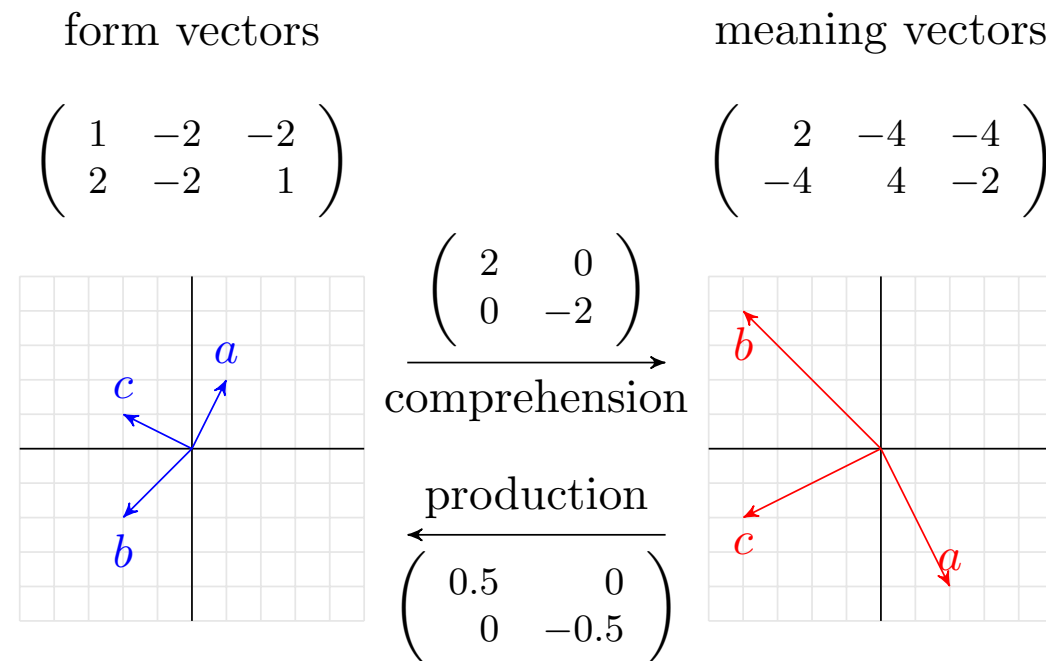


Figure 1: Word comprehension is modeled by matrix multiplication mapping form vectors onto meaning vectors, and word production is modeled by mapping meaning vectors onto form vectors.

audio of words excerpted from American TV news broadcasts, it recognised only 6% of the words presented to it in isolation. An LDL model trained on the audio of 10 hours of these news broadcasts performed with an accuracy of 8% (under 10-fold cross-validation). A cognitively motivated extension of the model resulted in an accuracy of around 13% (again under 10-fold cross-validation), substantially outperforming Mozilla Deep Speech.

Thus, LDL may prove useful as part of a speech recognition system for situations where context is unavailable. A major and as yet unresolved challenge for LDL is to get it to work not only for isolated words (as found in connected speech), but also for streaming connected speech. If LDL can indeed be extended in this way, it will provide an algorithm the carbon footprint of which is tiny compared to the unsustainably large carbon footprint of typical current AI solutions (see here at [MIT Technology Review](#)).

Another possible application is the assessment of the meaning of novel words, specifically, names for new inventions, technologies, and brands. Because LDL takes as input low-level visual or auditory features, it is able to project novel words into a high-dimensional space representing the meanings of existing words. A novel word's location in this space can then be used to evaluate what existing meanings it is most similar to, and hence what kind of associations and emotions it evokes.

Recent modelling results indicate that these associations are themselves predictive for both the speed of word recognition, and for how exactly speakers articulate novel words. These findings suggest that the model's predictions are precise enough for probing the semantics evoked by, for instance, novel brand names. <sup>(2)</sup>

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EBERHARD KARLS  
UNIVERSITÄT  
TÜBINGEN



**R. Harald Baayen**  
**Professor of Quantitative Linguistics**  
 University of Tübingen  
 Tel: +49 (0)707 1297 3117  
[harald.baayen@uni-tuebingen.de](mailto:harald.baayen@uni-tuebingen.de)  
<https://www.quantling.org/ERC-WIDE/>  
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# Cyber Security Lab of the National Research Council of Italy

The Cyber Lab of Italy offers research, training, education and communication to boost cybersecurity efforts across Europe, as the Institute of Informatics and Telematics (IIT-CNR) explain here

The Cyber Lab was established in 2017 to contribute to the national and international security ecosystem. The lab covers research, training and dissemination activities. The Cyber Lab covers research activities, training and education, networking and dissemination aimed at consolidating the lab as the main stakeholder in Europe.

It covers several research areas:

- **Cyber risk management:** Assessing the risk level of complex cyber infrastructures and defining the management of such risks.
- **Cyber protection:** Methodologies and techniques to protect the cyber world from attacks. It covers topics, ranging from IoT systems to large application domains such as smart grids.
- **Cybercrime and forensics:** This is the techniques for studying criminal activities in the cyber world and providing means for managing evidence to be used in forensic activities.
- **Cyber intelligence:** The strategies devoted to the collection and analysis of information from visible and dark web (including social media) for the protection of society.
- **Cyberattacks:** This area involves the study of how cyberattack methods

could be used to harm the cyber infrastructures at a national level.

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**“The lab covers usual education and training activities, as well as awareness and communication. The Cyber Lab runs, with the University of Pisa, a master in cybersecurity offering several courses from cloud security to cyber intelligence.”**

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In particular, the researchers currently coordinate two European Projects:

- The **European Network for Cyber Security (NECS)** addresses the training and development of a European talent pool to help implement and support the European cybersecurity strategy as highlighted in the EC’s Digital Agenda. Today, it is more important than ever to have researchers that combine a strong academic foundation with practical experiences, technological expertise with an awareness of the socio-economic and legal context and conviction to furthering research with an entrepreneurial spirit. The four-year NECS project for a cybersecurity research and training network makes a significant contribution towards meeting the increased demand for human expertise in this critical field. NECS fosters a multi-sector/multi-disciplinary approach that is absolutely necessary for coherently tackling all cybersecurity needs as recognised by the **Network**

**and Information Security (NIS) platform** that has been established by the EU in order to develop a public/private cooperation strategy.

- C3ISP’s mission is to define a collaborative and confidential information sharing, analysis and protection framework as a service for cybersecurity management. C3ISP innovation is the possibility to share information in a flexible and controllable manner inside a collaborative, multi-domain environment to improve detection of cyber threats and response capabilities, yet preserving the confidentiality of the shared information. The C3ISP paradigm includes collect, analyse, inform and react.
- **SPARTA is a novel cybersecurity competence network**, with the objective to collaboratively develop and implement top-tier research and innovation actions. Strongly guided by concrete challenges forming an ambitious Cybersecurity Research & Innovation Roadmap, SPARTA will tackle hard innovation challenges, leading the way in building transformative capabilities and forming a world-leading cybersecurity competence network across the EU. Four initial research and innovation programmes will push the boundaries to deliver advanced solutions to cover emerging issues, with applications from basic human needs to economic activities, technologies and sovereignty.



The lab covers usual **education and training** activities, as well as **awareness and communication**. The Cyber Lab runs, with the University of Pisa, a master in cybersecurity offering several courses from cloud security to cyber intelligence.

As a summation of the activities, the CNR Lab runs an observatory [Link - cybersecurityosservatorio.it] in cybersecurity where several services (often, the output of previous research projects) are offered in order to increase awareness and preparedness for all the main stakeholders, in particular, civil society and SMEs. The observa-

tory enables all interested parties to take advantage of the skills and the result of the laboratory activities through the publication of constantly updated information, documents, and services useful for knowing, understanding and reacting to cybersecurity threats.

Some of the services offered within the lab include – identifying levels of vulnerability, threat characteristics, studying, refining and implementing techniques and methodologies of network, systems and information security in order to increase the reliability and resilience of the systems.



**Fabio Martinelli**  
**Research Director**  
 Institute of Informatics and  
 Telematics (IIT-CNR)  
 Tel: +39 050 315 3425  
 Fabio.Martinelli@iit.cnr.it  
 www.cybersecurityosservatorio.it/en

# Strengthening cybersecurity in the U.S.

Here, we take a look at the work of the Department of Homeland Security when it comes to strengthening cybersecurity in the U.S., including the Cybersecurity and Infrastructure Security Agency Cybersecurity Division

Daily life, national security and economic vitality and in the U.S. depend on a stable, safe and resilient cyberspace, according to the Department of Homeland Security (DHS).

During November 2018, President Trump signed into law the Cybersecurity and Infrastructure Security Agency Act of 2018. This significant piece of legislation elevates the mission of the former National Protection and Programs Directorate (NPPD) within DHS and sets up the Cybersecurity and Infrastructure Security Agency (CISA).

“CISA builds the national capacity to defend against cyber-attacks and works with the federal government to provide cybersecurity tools, incident response services and assessment capabilities to safeguard the ‘.gov’ networks that support the essential operations of partner departments and agencies.”

One can see that such action is necessary because nation-states and sophisticated cyber actors take advantage of vulnerabilities to steal money and information and are working on capabilities to disrupt, destroy, or threaten vital essential services from being delivered.<sup>1</sup>

## Cybersecurity Division

The CISA Cybersecurity Division leads efforts to protect the federal “.gov” domain of civilian government networks and works with the private sector – the “.com” domain – to heighten the security of critical networks.<sup>2</sup> This occurs through the four functions listed below:

The National Cybersecurity and Communications Integration Center (NCCIC) aim to lower the risk of systemic cybersecurity and communications challenges in their role as the U.S.’s flagship cyber defence, incident

response and operational integration centre.<sup>3</sup> Since 2009, the NCCIC has served as a national hub for cyber and communications information, technical expertise, operating by means of a 24/7 situational awareness, analysis and incident response centre.

The Stakeholder Engagement and Cyber Infrastructure Resilience (SECIR) division within CISA streamlines strategic outreach to industry partners and government, by leveraging capabilities, information and intelligence and experts to meet stakeholder requirements.<sup>4</sup>

The Federal Network Resilience (FNR) Division plays a crucial part in providing direct cybersecurity support, communications and coordination to all Federal Executive Branch agencies. Their aim is to transform Federal Government cybersecurity risk management through operational governance and training, as well as encouraging effective collaboration.<sup>5</sup>

Concerning network security deployment, we know that CISA established the Network Security Deployment (NSD) division to serve as the cybersecurity acquisition and engineering “Center of Excellence” to encompass the entire DHS organisation.<sup>6</sup>

Currently, Jeanette Manfra is the Assistant Director for Cybersecurity for CISA and as such, she leads the DHS in their mission to strengthen and protect the U.S.’s critical infrastructure from cyber threats. As the sector-specific agency for the IT sectors in the U.S., CISA coordinates national-level reporting that is in keeping with the National Response Framework (NRF).<sup>7</sup>

## Strengthening America’s cybersecurity workforce

When it comes to cybersecurity in the U.S., it’s important



to note that in early May 2019, President Trump signed an Executive Order that directs the federal government to take critical steps to strengthen America's cybersecurity workforce. This action will bolster the mobility of the U.S.'s frontline cybersecurity practitioners and support the development of their skills to encourage excellence in the field. In addition, it will help ensure the U.S. retains its competitive edge in cybersecurity. It is also worth noting that today, there is a shortage of 300,000 cybersecurity practitioners in the country.

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**“CISA builds the national capacity to defend against cyber-attacks and works with the federal government to provide cybersecurity tools, incident response services and assessment capabilities to safeguard the ‘.gov’ networks that support the essential operations of partner departments and agencies.”**

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Acting Secretary Kevin K. McAleenan explains his thoughts on this Executive Order: “America's cybersecurity practitioners – whether working in the private sector or serving in the federal, state, local, tribal, or territorial governments – constitute a core element in our country's frontline defence and we must urgently bolster them in the face of a myriad of cybersecurity threats. DHS and this Administration are committed to bold action. From enabling movement between the private and public sectors to supporting our workforce's training, education and development, the President's action today sets the course to expand and sustain the workforce and ensure America keeps its competitive edge in the critical field of cybersecurity.”<sup>8</sup>

### National Critical Functions

In closing, we find out that in early May this year, the CISA releases the inaugural set of National Critical Functions.<sup>9</sup> In summary, these are supported or used by the government and private sector and as such, they are of crucial importance to the U.S, in that their disruption, dysfunction or corruption would have a debilitating impact on security, national public health or safety, national economic security or any combination of these.

Let's leave the last word to CISA Director Christopher Krebs who comments on cybersecurity risk, which is just one part of the CISA's excellent work. “Identifying these National Critical Functions has been a collaborative process between public and private sector partners and marks a significant step forward in the way we think about and manage risk. By moving from an individual, sector-specific lens to a more comprehensive, cross-cutting risk management framework, we can identify and manage risk in a more strategic and prioritised manner.”<sup>10</sup> ■

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# Cybersecurity in hospitals and care centres

Dr Peter Leitner, Head of Research & Innovation and Stela Shiroka, Project Manager at INTERSPREAD GmbH detail cybersecurity in hospitals and care centres and their thoughts on the need to move towards increased awareness and enhanced training capabilities in Europe

The advanced use of digital technologies in the healthcare field is leading to an increase of cyberattacks, data breaches and IT-driven security risks, making it an immediate requirement for the field to dedicate more resources to raising awareness and implementing protection measures. As such, we need to move towards increased awareness and enhanced training capabilities in Europe.

## Challenges and needs

The increased interconnectivity of medical devices and the proliferation of medical data has made the healthcare industry a very lucrative business for cybercriminals. Several reports indicate that healthcare is on top of all industries being mostly affected by cyberattacks. The most common form of incidents includes stealing patients' personal and medical records and encrypting them for ransom money to prevent medical staff from accessing patient information. Capable terrorists could also be able to render active medical devices deadly.

Still, the amount of funding and efforts allocated to cybersecurity in healthcare is very low, especially considering the costs arising for response and recovery from a potential attack.

An analysis of past attacks shows that more than 80% of them could have been prevented if better protection mechanisms had been in place. Modern approaches, strategies and tools are, thus, necessary to make professionals aware of the risks and to

support the organisations in implementing stronger protection measures. Training IT and management staff and raising awareness of the risks to all healthcare professionals is a key prerequisite thereof.

## Approaches and tools

To tackle current cybersecurity challenges in hospitals and care centres, training and awareness raising is an essential endeavour for achieving a common understanding of cyberthreats and security risks at all hierarchical levels. A few of the required approaches to tackle existing challenges include:

### 1. Awareness and empowerment

Each employee of a healthcare organisation is a potential target but also an important "sensor" in the context of cybersecurity. As such, awareness of cyberthreats and security risks is one of the most important factors to avoid human errors such as misdelivery of personal information, the general improper data management or destruction of vital data. Each organisation has to raise awareness to all its staff on cybersecurity, so it is not only considered as an "IT-only-problem". Elaborated cybersecurity plans need to be established, that assign everyone a certain role and display the importance for everyone.

### 2. Guidelines and handbooks

Comprehensive guidelines shall provide structured rules and policies on data handling, threat identification, risk minimisation etc. Handbooks have to be written and adapted to fit the

demands of the different target groups within a healthcare organisation considering their technical experience and skills. Effective cybersecurity management needs to identify individual users' challenges and increase the usability of guidelines and handbooks.

### 3. Training and workshops

Storytelling based training is an essential mean to overcome vulnerabilities in the system and to prepare staff for different scenarios. Training courses have to be tailor-made for each organisational unit. Besides training on the usage of software, hardware and the handling of devices, the safe sharing and handling of data and the consequences of wrong behaviours shall be an essential part of a modern cybersecurity training curriculum.

### 4. Showcases and practices

Showcases of common threats in each context of cybersecurity in healthcare can provide a better understanding of threats and individual risks. Gathering information on good and bad practices on effective cybersecurity management is, thus, a crucial element of staff awareness. Learning and monitoring of related industries in the health sector are essential to advance the protection of both critical environments and patients' data.

### 5. Assessments and checklists

Continuous assessments of all cybersecurity strategies, measures and systems are crucial and must be on the agenda of the management of all healthcare organisations. A

combination of internal assessments driven by the IT departments and cybersecurity professionals, as well as repeated assessments by external experts are recommended. To simplify the continuous monitoring of human and technical cybersecurity systems, the use of structured checklists is inevitable.

## 6. Solutions and software

Hardware and software solutions are crucial for each healthcare organisation. Widespread antivirus tools among all systems are only a first step. Modern healthcare infrastructures need threat assessment tools, network protocol analysers, intrusion prevention systems, etc. related to their individual organisation architecture, system specifications and repositories.

## 7. Advisors and catalogues

Intelligent digital advisors and smart solution catalogues are used to take quick decisions and find the right approach: a technical solution or professional service can deal with an accurate cyberthreat scenario. These smart assistants and advisors have to be backed by data and solution catalogues at a pan-European and international level to provide instant advice and foresight on upcoming trends in the field of cybersecurity.

# INTERSPREAD

**Dr Peter Leitner**  
**Head of Research & Innovation**  
 INTERSPREAD GmbH  
 office@interspread.com  
 www.interspread.com

**Stela Shiroka**  
**Project Manager**  
 INTERSPREAD GmbH

## PROFILE



# SECUREHOSPITALS.EU



## Raising Awareness on Cybersecurity in Hospitals across Europe and Boosting Training Initiatives Driven by an Online Information Hub

The SecureHospitals.eu project seeks to raise awareness on cybersecurity risks and protection opportunities in the healthcare domain. Through various training and awareness raising approaches, the project seeks to boost the level of training in cybersecurity in Europe, improve the knowledge of staff and, in turn, contribute to decreased vulnerabilities against cyberthreats and increased patient trust and safety.

### Knowledge aggregation and analysis

The project aggregates knowledge on existing cybersecurity practices across healthcare organisations, to analyse, elaborate and disseminate the information as a means of achieving common understanding among practitioners on best practices and strategies.

### Awareness raising and community building

By disseminating the acquired knowledge and creating a community of practice which continuously exchanges views, provides insights and collaborates in training, while delivering preparedness and response strategies in the future, the project develops an Open Information and Awareness Hub to bring together all relevant stakeholders.

### Training and capacity building activities

Aggregating the knowledge on the training gaps and needs of healthcare personnel, the project is creating training packages to be offered in the form of a Massive Open Online Course (MOOC), a summer school and several local workshops and webinars.

## PROJECT FACTS

**Programme:** Horizon 2020

**Type:** Coordination & Support Action

**Coordinator:** INTERSPREAD GmbH

**Duration:** 26 months

**Website:** [www.securehospitals.eu](http://www.securehospitals.eu)



This project has received funding from the European Union's Horizon 2020 Coordination & Research and Innovation Action under Grant Agreement No. 826497.



# Cyber-Trust: Safeguarding IoT and building trust through blockchain

Dr Stavros Shiaeles, University of Plymouth and Dr Nicholas Kolokotronis, University of Peloponnese discuss how Cyber-Trust is being used to Safeguard Internet of Things (IoT)

The explosive development of the concept of the Internet of Things (IoT) is accompanied by an unprecedented revolution in the physical and cyber world. Smart, always-connected devices provide real-time contextual information with low overhead to optimise processes and improve how companies and individuals interact, work, and live. An increased number of businesses, homes and public areas are now starting to use these intelligent devices. The number of interconnected IoT devices (wide-area and short-range IoT connections) in use worldwide has already exceeded 8.6 billion since 2018, and is expected to grow to 22 billion by 2024<sup>3</sup>.

On one side, the IoT devices offer extended features and functionality; on the other side, their security level is still low, with well-known weaknesses and vulnerabilities, which provide cybercriminals the opportunity to easily evade systems and eventually create backdoors into organisations' infrastructures.

Cyber-Trust is an innovative cyber-threat intelligence platform which aims to gather, detect, and mitigate sophisticated attacks, securing the ecosystem of IoT devices. The project is built around four pillars: Key proactive technologies such as zero-day vulnerability discovery and sharing; Cyber-attack detection and mitigation on IoT devices (tampering and net-



work/DoS attacks); distributed ledger technologies (DLT) to considerably reduce the ability of hackers to tamper with legacy IoT devices; and Interactive situational awareness and control to augment the infrastructure's operator capabilities in tackling risks and emergencies.

Most security issues arise from devices with flawed design or poor configuration, which allows attackers to compromise them<sup>2</sup>; tools, such as Shodan and IoTSeeker, can be easily used to discover such vulnerable devices. This raises the important question of how large-scale exploitation of such vulnerabilities can be prevented, considering the IoT devices' limited capacity to secure themselves as they cannot be equipped with operating systems or the multitude of security mechanisms available on systems with higher resource availability. Moreover, software update mechanisms to fix the vulnerabilities and

update configuration settings is often overlooked by manufacturers, vendors, and others on the supply chain.

In addition, even if such a functionality is given, there is often no efficient way to patch those devices, and the possibility to add new vulnerabilities exists. Many lists of "best practices" have been developed to address these issues. Building and managing vulnerability profiles, possibly with the involvement of manufacturers<sup>5</sup>, could assure consumers that security and privacy issues are addressed seriously. Realising this is far from trivial, the blockchain may prove to be ideal towards this direction.

In the project, we further advanced the current state-of-the-art on various areas such as the identification and linkage of cyber-threat exploits across different platforms by deploying and adjusting to our context a number of sophisticated methods and tools,

ranging from graph mining and anomaly detection mechanisms relying on machine learning, to the adoption of a permissioned blockchain to define a privacy-preserving framework for achieving trusted, decentralised coordination and transaction processing between IoT devices<sup>4</sup>.

Blockchain solutions have recently been proposed for both intrusion detection and forensic evidence applications<sup>1</sup>, since in both cases blockchain can solve issues pertaining to trust, integrity, transparency, accountability, and secure data sharing. To address the issue of trust establishment, the design of a blockchain-based solution for securing IoT devices and their transactions is not straightforward. In most cases, an IoT device's available resources are highly constrained, whilst there is a need for performing transactions at high speed. These requirements call for efficient blockchain solutions; key design factors that determine both their security and performance, in the context of the IoT, are briefly presented below.

Focusing on the blockchain, the project is utilising HyperLedger Fabric to build an independent Root of Trust (RoT) that allows the IoT devices to defend against sophisticated cyber-attacks, like Advanced Persistent Threats (APTs). This is achieved by storing the update history of an IoT devices' integrity state in the distributed ledger, since the primary advantage of using the blockchain for integrity is that there are no keys to be compromised.

The main assumptions under which such mechanisms are secure is the transparency of the data stored on the blockchain and the utilisation of a cryptographically strong hash algorithm whose fingerprint is included in the blockchain<sup>1</sup>. The choice of Hyper-

Ledger Fabric was not random as well; the key advantage of HyperLedger for Cyber-Trust is the private channel feature that allows to partition the data added on the blockchain. Due to the criticality of the stored data, only users that have subscribed to a channel should be able to access its content.

Another asset of HyperLedger is its scalability which is an important factor if we consider that the ecosystem of Cyber-Trust is estimated to be 22bn IoT device by 2024<sup>3</sup>. The technology used needs to have a high transaction throughput and for that reason Kafka is used in HyperLedger to propagate transactions having previously been validated by smart contracts. Kafka acts as a queue inside the central peer of the permissioned distributed ledger, which is run by a trusted host, most likely, the Cyber-Trust back-end; using a queue like Kafka, removes any single point of failure due to the centralisation of the system. Due to having adopted a private blockchain, which can be controlled by a smart contract and a central ordering service, we may assume that the nodes are unlikely to be malicious (but still take measures to prevent any dishonest behaviour). The mechanism used is close to a proof of Authority consensus.

Cyber-Trust and its results will prove to be valuable in fostering solutions offering built-in resilience, which will help stakeholders to better protect their assets against (and recover from) large-scale advanced cyber-attacks. Thus, positive impact will be generated not only for European citizens and small and medium-sized enterprises (SMEs), but also for Critical Information Infrastructures (CIIs), law enforcement agencies (LEAs), and computer security incident response teams (CSIRTs) with the following key aspects: improved knowledge concerning the detection and mitigation of large-scale

cyber-attacks targeting at critical infrastructures, improved solutions for the acquisition of forensic evidence, innovative tools for easily embedding cyber-security in future technologies and products, and most importantly, increased trust in using the services being offered by IoT platforms.

## Acknowledgement



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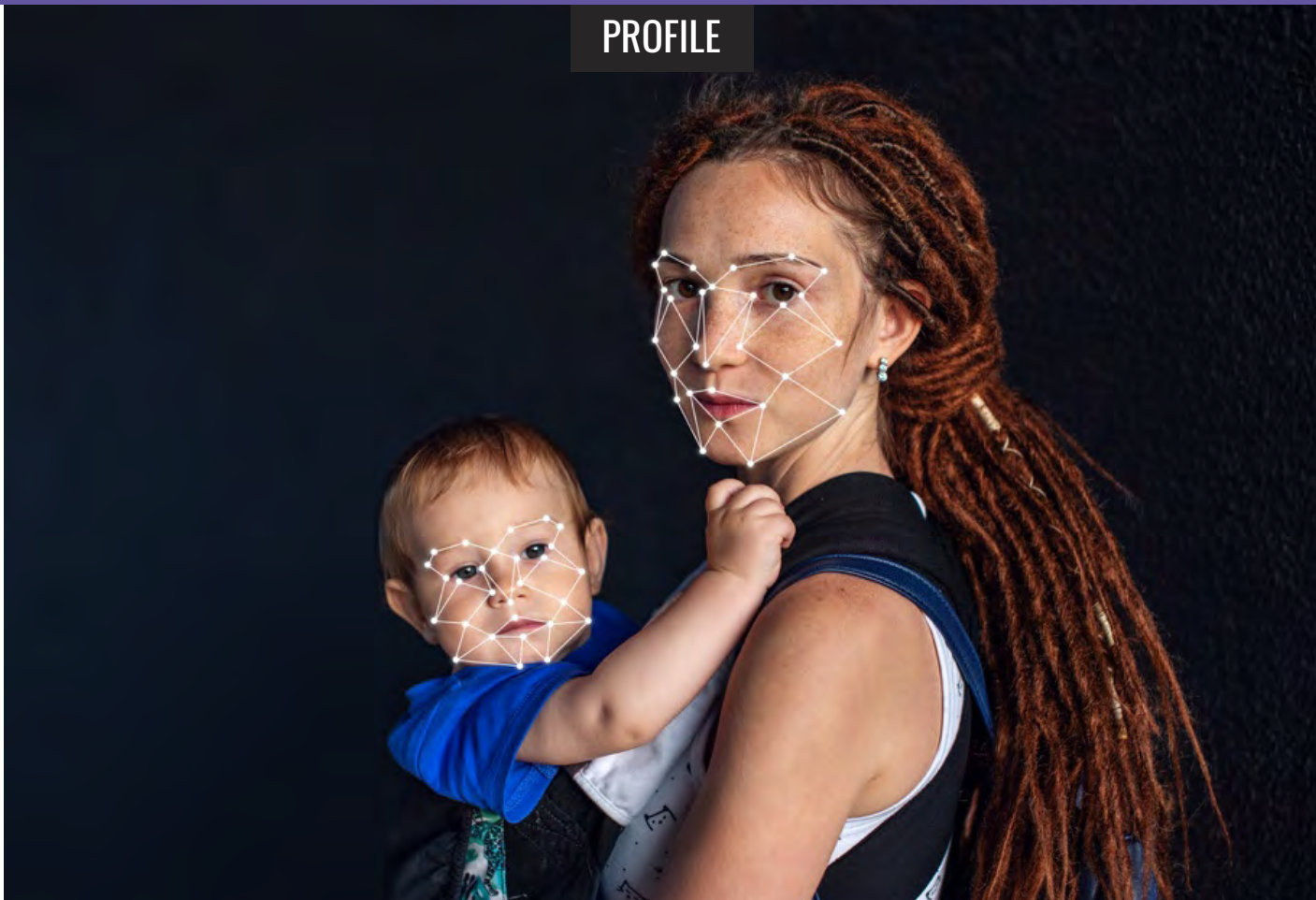
<https://cyber-trust.eu/>

## Dr. Stavros Shiaeles

Centre for Security, Communications and Network Research, University of Plymouth, UK  
Tel: +44 (0)1752 586 322  
[sshiaeles@ieee.org](mailto:sshiaeles@ieee.org)  
<http://shiaeles.info>  
[www.linkedin.com/in/stavros-shiaeles](http://www.linkedin.com/in/stavros-shiaeles)

## Dr. Nicholas Kolokotronis

Department of Informatics and Telecommunications, University of Peloponnese, Greece  
Tel: +30 2710 372231  
[nkolok@uop.gr](mailto:nkolok@uop.gr)  
<http://www.uop.gr/~nkolok/>



# Cybercrime, illegal content online: We don't have to turn a blind eye

Marsali Hancock from EP3 Foundation underlines that we don't have to turn a blind eye concerning cybercrime, illegal content and harmful activities online

**A**s we connect new generations of children and communities online, our unique opportunity is to be the generation that implements new, additional, privacy-protecting designs and protocols. Cybercrime, illegal content and harmful activities don't have to threaten our national security or the physical safety of our children.

Information and communications technologies (ICTs) enable world citizens to instantly access digital systems that have the potential to create better standards of living, improve health, save lives, educate, entertain

and inspire. For the three billion of us who have access to the Internet, very few of us could imagine living productive lives without Internet connectivity. And many of us live, eat and breathe access to online systems that define careers, family life and for many, our very identity.

The world, with its circumference of over forty thousand kilometres, has shrunk to the size of our hand-held devices and we are able to go anywhere, see anyone and do anything at the touch of a screen. And therein lies not just the bright future of our children but also the concern

for their safety and well-being. The vast potential the Internet holds for billions of people across the world is balanced by the responsibility to use this tool in the most effective and responsible manner possible, especially when safeguarding the world's children.

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**"As we are at the midpoint of connecting the entire world, it's time to consider how we are doing at reducing cybercrime and child exploitation."**

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Against that backdrop, responsible digital skills and enhanced cyber wellness are increasingly important in



a civil society. Information superhighways bring more than just convenience. Studies suggest that a 10% increase in internet penetration is correlated with a 1.35% increase in GDP for developing countries GDP. However, the superhighways also bring cybercrime, exploitation and radicalisation.

The list of risks could be considered overwhelming. Online predators and cyber-stalkers pursue and prey on children. Impressionable youth are the victims of bullying, cyber-attacks and fraud. Terrorist cells have discovered that the internet can promote their activities and methodologies and also act as an effective recruitment tool among the younger generation. Sexual violence and other harmful products and problematic behaviours are exacerbated by their almost effortless accessibility. Additionally, intellectual property theft and identity theft have repercussions that could harm a person for decades.

As we are at the midpoint of connecting the entire world, it's time to consider how we are doing at reducing cybercrime and child exploitation.

New tools and privacy-protecting data practices are, therefore, required.

When first connected, children need protection. Digital skills, alone, cannot substantially reduce the risks from children's access to harmful content or being targeted and groomed for sexual exploitation and radicalisation. New data paradigms are required to shield them and protect them from their own youthful experiences and indiscretions, including self-generated

content. To thrive, they must understand this new environment, but we also need to implement ways to protect them. We cannot completely control what they consume online, but we can protect who sees their actions online.

Every action they take is tracked online, whether it's because of cookies, web beacons, or e-tags. Offline, teens have their movements tracked by new sensors in devices, loyalty programmes or discount codes. Each action carries a code that enables companies to track and sell that data and since it is connected to the child, their actions can be revealed to malicious entities, such as hackers.

It is vital to establish new systems to protect our children and ensure the internet serves as a driver for innovation, scientific research, economic growth and social development. How we manage the internet and the deployment of the Internet of things (IoT), artificial intelligence (AI), blockchain and other distributed ledger technologies (DLT) will determine whether our society is able to move toward an internet that benefits all people around the world.

What better way to do this than to hide the identity of the child and only send out relevant data to companies rather than every action the child has taken?

Rather than tracking everything the child does online, EP3 Trusted Data Networks break down the data to the attribute level, keeping the information, but hiding the identity of the child. This still gives organisations

access to important data that could track societal trends but never reveals the child's identity. The only way for the child's identity to be revealed is for a trusted identity to directly ask the child to reveal it. Once they have this layer of protection, guardians and parents can then support and protect their child from risks they can manage, such as cyberbullying.

There are many risks associated with going online, but we can take steps to protect our children from malicious entities. It may be a challenge, but we can do something to protect our children online. After all, "the power of the Internet hinges on users' willingness to trust it" and in the end, use it for the benefit of all. <sup>(1)</sup>

(1) See Supra. Internet Society, 2017 Internet Society Global Internet Report: Paths to Our Digital Future, (2017) p. 72.

## EP3 FOUNDATION

**Marsali Hancock**  
EP3 Foundation  
Tel: +1 4088 007 202  
marsalih@gmail.com

# In a perfect partnership: How councils can get the most out of a tech provider

London Borough of Barking and Dagenham Council's Cassandra Phillip lists the key steps to creating a successful partnership with a technology provider

In local government, digitisation of systems can sometimes be viewed as disruptive, can require significant investment and there's often a perception that it can lead to a great deal of extra work for all involved.

But the implementation process doesn't have to have a fear-factor for Local Authorities. In June last year, London Borough of Barking and Dagenham Council (LBBD) were looking for a new case management system which could reduce the administrative burden impacting its school admissions teams. The Council was operating with a minimum six-week backlog during the Sept/Oct period and also found that our existing technology provider, who we'd been working with for over five years, had become unresponsive.

The new case management system that we chose from [Servelec](#) underlines the importance of technology in local government and was installed and fully functioning after just four weeks. It immediately enabled much closer communication between us and schools. We could see the interaction and the immediacy between us and schools and we loved it.

The system is an example of technology that has been designed to help local authorities to support families more effectively by spanning the full education and child services spectrum. It has already proved to be a vast improvement on the existing system, based on the 87% increase in applications received between July 2017-Jan 2018 versus July 2018-Jan 2019. We've now managed to reduce the backlog by four weeks. LBBD has come forward in leaps and bounds.

So, how can councils work with technology providers to achieve smooth implementation? Here's what you should look for:

## 1. Experience, support and reassurance

When looking for a supplier, experience is everything. Historically, LBBD had been part of the Pan-London Register, where all London Authorities have adopted the same system. The admissions element of this system was no longer fit for our requirements, so we got to know a few local authorities who used both different and similar systems to us. The product we chose is the flagship solution, which ultimately was reflected in the impartial decision taken during the procurement process.

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**"For most local authorities, when we make an investment in technology, we want to see a return on investment (ROI). We also want to see clear potential for future development and most importantly, the potential for interoperability. When making any technological purchase, these key aspects need to be considered."**

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Throughout the implementation process, there were a whole team of consultants who offered advice, guidance and continued reassurance throughout the very short implementation period.

## 2. Ability to be flexible

Every local authority has its own nuances and idiosyncrasies around the way they work and manage projects and our tech provider was fully accepting of that and accommodated our working style.

Of course, the tech needs to be flexible too... our new system has the ability to ensure in-year applications can be made online and that data is downloaded into the local authorities without the need for re-keying information. Outcomes are sent to parents effortlessly and securely, again without the manual process of producing letters, which are then automatically saved



to the child's individual file without further work for the admissions officer.

### 3. Potential to future-proof

For most local authorities, when we make an investment in technology, we want to see a return on investment (ROI). We also want to see clear potential for future development and most importantly, the potential for interoperability. When making any technological purchase, these key aspects need to be considered.

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**“It has already proved to be a vast improvement on the existing system, based on the 87% increase in applications received between July 2017-Jan 2018 versus July 2018-Jan 2019. We’ve now managed to reduce the backlog by four weeks.”**

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Although admissions sit independently at LBBB, the council are also using the new case management system within the EHC team and Family Information Services, so multiple information can be brought together, creating a single view of the child.

Our relationship with our provider is now going one step further as we want to collaborate with them to evolve the system to ensure it responds even more intuitively to users' requirements.

Developing a partnership, rather than a transactional relationship with suppliers and vendors, particularly those in the tech sector, will, in my opinion, create a support network for LAs, ensuring we purchase, implement and develop the best tech for our requirements. ■

#### **Cassandra Phillip**

#### **Admissions Project Manager, School Admissions Team**

London Borough of Barking and Dagenham Council

<https://www.lbbd.gov.uk/>

[www.twitter.com/lbbdcouncil](https://twitter.com/lbbdcouncil)





# A LOST PAST

# RECAPTURED

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A FORGOTTEN  
LEGACY

at the  
touch of a  
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# Why digital transformation in education matters

Peter Richardson, Senior Marketing Manager PFU (EMEA), explains why digital transformation in education plays a crucial role

When the Final report of the Commission on Assessment without Levels was released, it recommended that schools should build an assessment framework to check what pupils have learned and whether they are meeting expectations, and to report to parents and other stakeholders.

A significant part of this system is collecting assessment data, however, the report acknowledged that many teachers found data entry and management in their school burdensome. This is where the right technology solution can make a difference.

## Capturing evidence of progress

Technology can play an important role in capturing the detail of students' work, which helps teachers and parents monitor how a child is progressing. By documenting handwriting and creative work, for example, comparisons can be made at intervals against content already stored digitally, leading to a better understanding of who is improving and who requires more attention.

In addition, when schoolwork is available digitally it can be more easily shared. Some schools already capture all student content each day and share it directly with parents, instead of requiring children to take home physical documents.

## Supporting school administration

Document capture solutions also help schools' administrative duties, such as managing permission slips and invoices. An OCR-enabled (optical character recognition) scanning device can extract the relevant data from the forms, saving time on manual data entry. Some universities also use this technology to capture data on lectures.

Instead of asking students to complete online forms to provide post-lecture feedback, they are given paper versions in the room. These are then scanned, and the information captured digitally, which is leading to higher response rates and helping to improve teaching.

## Reaching the right stakeholders

Schools that cater for excluded and special needs students face additional challenges as they often have to liaise with a range of stakeholders, such as the SENCO (special educational needs coordinator), child services, councils, other schools and the students' parents, who each regularly require different datasets.

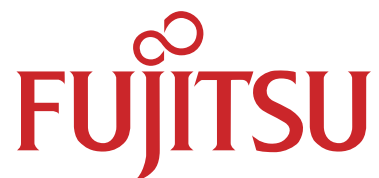
By digitising documents used by, and about, school children – and harnessing OCR – these schools can capture all the necessary data at once and, by using the right solutions, send that information directly to the relevant party safely and securely.

## Data compliance

Under new laws, individuals have the right to access their personal data. This is commonly referred to as 'subject access requests' and, while schools currently only receive very few, this is expected to increase. With much of the information currently only available in paper format, responding to such requests is time-consuming and could potentially lead to non-compliance if the requested data cannot be found. Paper records are also less secure than a fully managed digital platform, and security is an issue teaching institutions must address now that the general data protection regulation (GDPR) is in place.

By implementing digital working practices, including the scanning and digitisation of administrative and student material, schools can very quickly see the benefits that they bring to staff members, pupils, parents and wider support personnel.

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**Peter Richardson**  
**Senior Marketing Manager**  
 PFU (EMEA) Ltd  
 Tel: +44 (0)208 573 4444  
[peter.a.richardson@uk.fujitsu.com](mailto:peter.a.richardson@uk.fujitsu.com)  
[scansnap@it.com](mailto:scansnap@it.com)  
[www.twitter.com/28Vaughan](https://www.twitter.com/28Vaughan)

# Blockchain: A revolution in marketing

In this article, Harnil Oza explains how Blockchain technology is improving the world of marketing via information tracking, influencing consumer expectation and embracing transparency

**B**lockchain technology was perceived by many as a global revolution in many areas, as well as a tool used by drug dealers and smugglers.

In reality, blockchain is a fascinating invention that can change the world.

Imagine blockchain as a distributed book, which is located simultaneously on all devices connected to its network. Whenever the data register is changed, the information is updated on each of these devices. This network method of tracking information has supported the growth of decentralised digital currencies such as Bitcoin and Ethereum.

But the blockchain has many potential applications in other areas that have already begun to shape certain consumer expectations, a market entry strategy and data collection. Moving forward, the revolution that blockchain technology has begun will force large companies to position themselves differently in the modern world, where decentralisation and transparency will become important components.

## Changes in consumer expectations

Consumer expectations are already changing as a result of the release of tools, such as HybridBlock, which provide users with information about blockchain and cryptocurrency. They can train newcomers in this field and provide them with all the tools for career advancement in order to become more qualified and savvy.

As consumers and companies learn more about blockchain opportunities, they will begin to choose products and services that are decentralised. For example, the launch of the OPEN Platform project in Silicon Valley provides a turnkey solution for the integration of block networks between on-chain and off-site applications. This means that developers, marketers and companies will be able to create

marketing tools and applications with minimal knowledge of how a blockchain is organised.

OPEN CEO Ken Sangha says that they understand what the next wave of marketing applications could be and that CMO (chief marketing specialists) will focus on blockchain technology and cryptocurrency. He noted that blockchain technology is designed to securely and transparently exchange data between a large group of people without the need for centralised oversight to ensure data security.

Through the use of the blockchain, customers will be able to control how the campaign processes certain data, or to track the origin of a particular item. Blockchain provides consumers with the platform they need to make centralised institutions more open and accountable to society.

## Capital becomes more affordable

According to the report of CB Insights, the second most common reason for the failure of start-ups is that their creators simply “run out of cash”. At the same time, they are in dire need of funds to promote marketing campaigns. But now, they can use the new way of financing their ideas.

Thanks to the introduction of blockchain technology and cryptocurrency, start-up developers now have access to capital through tools that have not existed just a few years ago. As an example, it's enough to take TrustToken, a technology that allows people all over the world to buy a stake in real estate or small businesses.

Each asset or business can acquire its own token, which will be traded on any cryptocurrency exchanges, such as Ethereum or Bitcoin. TrustToken technology can help with auditing asset ownership and control of each transaction, resulting in a blockchain strength that will improve traditional markets around the world.





*Harnil Oza, CEO*

### **Evaluation of customer attitudes on demand**

Leading global technology companies are investing billions of dollars in the development of artificial intelligence (AI). Amazon founder Jeff Bezos recently announced that his company is going to double its work in the field of AI-based technologies, which will revolutionise the interaction of consumers with manufacturers.

But small businesses are at a disadvantage when it comes to developing technologies based on AI. While large companies own a huge amount of data with which they can combine machine learning algorithms, small organisations cannot boast of it.

With a blockchain, consumers and companies will be able to buy and sell data through decentralised, but very transparent markets. Synapse is one such platform that allows consumers to sell their data in exchange for SYN tokens and customers to track individual users. On a broader scale, this can help create a dynamic AI ecosystem that can become smarter and more efficient over time. Ultimately, this will lead to a completely new AI-based economy.

Iris is another blockchain-based platform designed to allow consumers to sell their data (in this case, health data). At the same time, it allows researchers and corporations to access large databases on demand. With proper stimulation, this platform can serve as evidence that consumer data can be shared on mutually beneficial terms.

Another company in this area is ClearPoll, which uses blockchain technology to safely record respondent choices. It also allows organisations to test different ways to stimulate customers and obtain client opinions.

Respondents get rewarded for their participation in the survey, which makes it easier for manufacturers to assess customer opinion when using POLL tokens. ClearPoll also offers detailed survey data from a database of several thousand different polls.

### **Adaptation of brands to the successful use of blockchain**

The blockchain revolution will gradually expand. Just as it changed the situation in the field of content and commerce, it will be able to change the customers' expectations regarding the producers over the next few years.

While today, it may seem like a relic of libertarians and technicians, powerful and secure technology is becoming increasingly popular. As a result, manufacturers who adopt the principles of revolutionary technology will win in the struggle for potential customers who are interested in supporting innovative companies.

Large companies already go hand in hand with blockchain and look to the future. For example, Burger King released its own blockchain-based cryptocurrency and IBM is helping Chinese retailers improve product security.

If you think that you need to think only about technologies, such as augmented reality and machine learning, you might miss out on the opportunities that blockchain offers.

Blockchain is already here and it is not going anywhere. This means that marketers have new perspectives and opportunities for communicating with consumers, raising capital and collecting data.

But, above all, this means that marketing leaders must embrace all of these innovations since decentralisation and transparency are becoming the norm in modern society. ■

### **Harnil Oza CEO**

Hyperlink InfoSystem

Tel: +91 8000 161 161

info@hyperlinkinfosystem.com

www.hyperlinkinfosystem.com/

www.twitter.com/hyperlinkinfo

# Closing the global trade finance gap with a blockchain solution

Here, we find out that InventoryClub, a Commonwealth-focused trade finance application developer, is re-inventing trade finance in global trade, beginning with a blockchain platform to support a thriving trading community

The estimated \$1.5 trillion deficit in the annual global trade finance requirement and complex trade flow systems are failing micro, small and medium-sized enterprises (MSMEs) in the world's southern Commonwealth countries. It's not that the capital doesn't exist, it does. It's become a question of freeing up the funding that's locked-down behind intense regulatory and compliance requirements and redefining perceptions around trading with MSMEs, particularly producers and manufacturers in South America and Africa.

Forming a vibrant ecosystem of distributed ledger technology (DLT) applications to manage product inventory warehousing, promote peer-to-peer member financing and encourage cross-border trade among businesses of all sizes in Commonwealth countries, InventoryClub has designed a platform and process for enabling financial inclusion and equity. Through the InventoryClub platform, smaller-scale producers and manufacturers have access to competitive markets and can accordingly set their own prices which are visible to members willing to finance their trade.

Terry Igharoro, founder and CEO of InventoryClub, is driven to solve the problems of global trade finance, to connect sellers from smaller Commonwealth states with buyers from around the world, while mitigating risk through

the use of smart contracts. He clarifies: "InventoryClub is bridging the \$148 billion trade finance funding gap in emerging economies with our non-credit based peer-to-peer trade finance platform. Where the banks and global financial sector have failed MSMEs we believe the people will succeed. The African diaspora accounted for \$66 billion in remittances to the continent in 2018 and its predicted peer-to-peer lending will reach up to \$897 billion by 2024. The global commodities market is valued at approximately \$30 trillion so we're focusing our efforts on providing an alternative market to connect producers with merchants backed by global financiers, which in turn enables them to move up the value chain and claim a bigger slice of the pie."

## Access to finance

Vital for the creation and continual growth of the economies of the world, access to finance can make all the difference to the traction a company gains within a market. Accomplished multinationals with firm track records tend to dominate as banks and venture capital organisations provide these large enterprises with diversified funding options while MSMEs find their prospects of accessing finance appropriate to their level of innovation and business size are severely limited. In particular, small businesses in emerging economies face more pronounced funding gaps than are

found in well-developed countries. Many MSMEs do not have access to traditional credit options provided by banks and venture capital firms.

While in recent years, there was some improvement in the economic environment in which MSMEs operate, including their finding it a little simpler to access credit, banks have also modified their business models and adopted stronger credit selection criteria. Higher interest rate charges attach to MSMEs perceived as having higher risk profiles. Micro-enterprises, innovative start-ups and businesses based in rural or remote areas are among those who are commonly excluded from any formal sources of external finance.

## Stronger financing structures

While trends head toward business environments with less credit, rigorous rules and regulations are on the increase. In this climate, it is ever more urgent to reduce the dependence of MSMEs on borrowing as a model and to replace this with ever-green capital structures that improve the resilience of emerging economies. Along with alternative finance instruments, better trade finance models that lower perceived risks and improve opportunities for gain by all parties involved in a transnational trade are on the rise. Allowing a seller to set his own price, financial backers



and traders who fairly connect buyers to sellers to obtain satisfactory marginal profits and a buyer to pay a price he is prepared for, one that is standardised by a competitive market.

**“InventoryClub is bridging the \$148 billion trade finance funding gap in emerging economies with our non-credit based peer-to-peer trade finance platform. Where the banks and global financial sector have failed MSMEs we believe the people will succeed.”**

While some MSMEs in emerging Commonwealth nations have improved access and availability to alternative financial instruments, many are averse, for example, to losing equity to obtain it. Building a system for trade finance on a decentralised blockchain, where identity data, inventory data, shipment tracking and the tracking of individual products from one geophysical location on the globe to another are all possible, has the potential to simplify the cumbersome paper-based systems that are the legacy of international trade, provide

full provenance data and render transparent the finance and pricing structures within an industry.

## Digital and financial inclusion

Emerging economies in smaller member state countries, such as those in Africa and South America that have sufficient infrastructure to access DLT solutions, which provide a frictionless money-transfer experience backed by an ecosystem that supports effective trade across borders, may benefit from InventoryClub’s platform and process for ensuring widespread digital inclusion. DLT’s promise of cost reduction increases margins while the consequential nature of the trust structures inherent in smart contracts and the decentralised ecosystem allows members to back trades that they may not have in legacy systems. Alternative valuation systems, inventory financing and receivables discounting are a few of the mechanisms that may be made available to members within a digital trade finance community.

The development of DLT and blockchain solutions which counter collateral shortage and information asymmetries through innovation and which display a drive toward equity are proving a popular space for MSMEs to enter competitive markets with confidence. Through 2019, InventoryClub is progressing with the growth of its InventoryClub platform for peer-to-peer financing, the ComodX marketplace and VNTPay applications, reducing barriers to entry for many MSMEs in the Commonwealth.



**Terry Igharoro**

InventoryClub Ltd

[terry@inventoryclub.com](mailto:terry@inventoryclub.com)

[www.inventoryclub.com](http://www.inventoryclub.com)

[www.twitter.com/inventoryclub](https://www.twitter.com/inventoryclub)





# Blockchain and retail: A potential industry revolution

This article discusses the potential of blockchain and retail: Could the technology be responsible for a profit increase for the sector in 2018?

In the three months to January 2019, [ONS](#) reported that the retail sector saw a slight profit increase of 0.7%. The year before that, the same source highlighted a decrease in the number of stores opening.

Analysts predict that online competitors, rising staff costs and consumption fatigue could all contribute to its decline. Could blockchain provide a solution?

The open ledger makes permanent records of transactions and was originally used for cryptocurrency purchases.

This means that any payment of contract can be transferred online – which could transform the industry. Here, we examine how.

### Legal protection

Blockchain automatically produces digital records of transactions. In turn, it can speed up returns and refunds operations. This doesn't just reap practical rewards for users – it can be beneficial from a legal standpoint, too.

Retailers will no longer need to store data – either manually or on PC – themselves; the blockchain system will do it for them. And the right contract can help to authenticate product data immediately, should a customer demand it.

This could make transport and shipping easier for many retailers. Food market chains, for example, are already using it to track food items.



Thanks to [retail law firms](#), advice on how to maximise the advantages of blockchain are easily accessible. Industry members that do look to legal experts could heighten their overall performance.

### Clear supply chain

Ethical consumerism is on the rise throughout the world – especially in the UK. The 2019 Organic Market report revealed that the sector makes a profit of almost £45 million a week.

### The Soil Association

[The Soil Association](#) – who conducted the survey – also highlights that last year saw a growth of 14% in sales for beauty and wellbeing products within this sector.

Increasingly, people are wanting to know where food has come from, not just how it has been produced. Luckily, blockchain can meet this demand.

This is largely because its documents are unalterable. Retailers that use this payment structure are unable to modify goods purchase records to appease customers – blockchain won't allow it.

Thanks to it, consumers can identify the exact source of their meal, make-up, or clothes. More retail firms are looking to Blockchain to grow their business. Those that do must adhere to moral standards in order to gain a higher client satisfaction rate.

With a clear supply chain, these agencies are able to evidence their commitment to responsible shopping. This may enable them to score highly in customer surveys – and could generate more sales as a result.

### Customer security

Private blockchain accounts can only be accessed by cryptographic key holders. To anybody else, they're impenetrable. For this reason, this system could deliver a safer alternative to traditional payment methods.

In-store transactions can require customers to share certain bank details. Similarly, online payment options typically ask shoppers for personal information.

Because they guarantee information security, retailers that use blockchain can deliver a better option. Consumers may be more inclined to pay through this system.

So, we could see clients opt for concrete and web stores that offer this service. Could this give retail a much-needed popularity boost?

Creations like blockchain make this an [exciting time for the industry](#). Thanks to this process, there are plenty of opportunities for growth and expansion. It may even help the high street to make a comeback. Surprisingly, the technology could hold the key to the future of retail. ■

**Beth Andralojc**

# Decentralising security for mobile devices: Is blockchain the viable solution?

Steven Sprague, Cofounder and CEO of Rivetz reveals a viable solution when it comes to decentralising security. He argues that there is great promise for creating mobile device security with blockchain technology

The world was introduced to the first commercial mobile phone in 1983 with the launch of the Motorola DynaTAC 800x, which stood at a height of 13 inches, weighed 1.75 pounds and took 10 hours to recharge. In the early days of the mobile phone industry, it was incredibly simple for attackers to clone a phone's identity and run up all sorts of charges on your account.

Over the last few decades, mobile has experienced quite a metamorphosis from the "brick" of the 1980s to the compact, feature-packed smartphone of today. Now, mobile is king – people across the globe use their mobile devices not only to communicate but also to read the news, get directions, stream music, check bank accounts, store assets and so much more.

As we increasingly rely on our mobile devices, new avenues of attack continue to emerge. So much of our sensitive personal information and digital assets – such as corporate data and bank account and credit card numbers – are accessible via our mobile devices. They have become treasure troves for attackers.

## Blockchain and mobile device security

There is great promise for creating mobile device security by combining secure enclaves – also known as 'roots

of trust' – with blockchain technology. Blockchain is a distributed ledger technology that protects a digital transaction through complex mathematical algorithms. Because of the strength of this math, the transaction can only be created by those who hold a valid private key.

Private keys were developed as a means of protecting our digital transactions. A private key is a piece of cryptographic code that allows a user to prove who he or she is – in other words, it's a digital signature that says the user is, in fact, the one who is executing a digital transaction.

Private keys are used to secure a variety of transactions on mobile, including messaging, cryptocurrency and more. Here's the downside: if an attacker steals your private key, they can impersonate you, and then access and abuse your data and digital assets. The prevalence of mobile devices has made them some of the largest repositories for private keys.

The biggest challenge in decentralised cybersecurity is that we cannot prove the transaction was intended. If an attacker steals your private key and transfers \$5,000 to a third person, there is no way to prove that the attacker – and not you – performed the transaction. Rivetz ensures an intended transaction by establishing

that it occurs from a known device, in a known condition, with an authorised user, under the required conditions. Rivetz performs "device attestation" to ensure a user's devices are in a "known" condition by executing regular health checks to ensure the device integrity. Each device's integrity is recorded on the blockchain so future health checks can be compared with the baseline, establishing that those devices are in a condition the user intended.

As the rise of the internet brought digital fraud and attacks on identity, innovative industry leaders banded together to fight that fraud and formed organisations such as the Trusted Computing Group (TCG). TCG developed specifications that have become standard for securing devices, as well as the data and identity on those devices, such as personal computers and laptops.

Trusted computing uses hardware to protect users. It ensures a device will consistently behave in the expected ways, protected by a secure enclave or a 'root of trust' embedded within the device's hardware. A root of trust is isolated from the device's software operating system (OS), allowing it to execute code that cannot be seen by the OS. One such root of trust developed by Global Platform is the Trusted Execution Environment (TEE), which





enables trusted computing technology for mobile devices. The TEE already is built into the hardware of more than 1 billion mobile devices. Today, most private keys are generated within software, which is much more susceptible to attack than hardware. The TEE is capable of protecting a user's private key within the device hardware, a method that is far more secure than performing these operations in standard software.

A single system of security may not be enough to protect against the variety of cyber-attacks possible today. It is more pressing than ever to provide multi-layered protection of digital assets across two or more security domains. That way, even if an attacker were to breach one point of security, the other(s) still would need to be compromised, offering an extra layer of protection for important digital assets – whether that's your personal information or your hard-earned money.

One of the most ubiquitous roots of trust is the subscriber identity module, or SIM card. The SIM is a protected hardware environment and was created to combat mobile fraud and to protect the device identity. With the pervasiveness of both the TEE and the SIM, Rivetz saw an innovative opportunity to use these isolated roots of trust to work together to protect mobile users. In conjunction

with ElevenPaths, the cybersecurity unit of Telefónica, the world's third-largest mobile carrier with more than 300 million subscribers, Rivetz uses both the TEE and SIM to protect our private keys – introducing the Dual Roots of Trust.

The solution leverages the TEE along with the SIMs deployed by Telefónica. With Dual Roots of Trust, Rivetz-enabled apps generate private keys in hardware, then cryptographically distribute those private keys between the TEE and the SIM. This delivers built-in security from both the mobile carrier and the device manufacturers, to create decentralised key protection.

By distributing a private key across these two roots of trust, attackers would have to breach both secure systems in order to steal a single private key. As an added security feature, two different entities – or independent control planes – aid the user in controlling their private keys. Through a special application authorised to perform activities inside the TEE, the user remains in control of the secrets stored in the TEE. If your mobile device is lost or stolen, a simple interaction with your mobile carrier can disable the SIM, permanently or temporarily until the device is found. So even if a thief has your device, you remain in control and your private keys are still safe.

The Rivetz solution has an unlimited number of use cases, such as sensitive work apps, mobile wallets, social media accounts and mobile banking. One of the most unique applications of Dual Roots of Trust is the ability to provably control specific applications on a device. This feature is especially useful for enterprises. Let's say a company has its own proprietary Rivetz-enabled app that employees use for work on their personal devices. If an employee is terminated or leaves, the company has the ability to revoke access to that app on the former employee's personal device with Dual Roots of Trust.

As our mobile devices have become more important to our everyday lives and contain so much of our personal and private data, we need better ways to protect ourselves. The solution lies in the roots of trust that already exist on millions of mobile platforms: the SIM and the TEE are two of the most common secure enclaves. Dual Roots of Trust is the next step in ensuring our assets stay safe.



**Steven Sprague**  
Cofounder and CEO

Rivetz  
sales@rivetz.com  
<https://rivetz.com>  
[www.twitter.com/rivetzcorp](https://twitter.com/rivetzcorp)

# Why are central banks leading blockchain experimentation?

Here, the World Economic Forum discusses how central banks are among the most cautious institutions in the world, yet the first to implement blockchain experimentation

Central banks have been quietly researching its possibilities since 2014. Over the past two years, the beginning of a new wave has emerged as more central banks launch large-scale pilots and research efforts, including rapid and complete cross-border interbank securities.

The Blockchain and Distributed Ledger Technology team at the World Economic Forum interviewed dozens of central bank researchers and analysed more than 60 reports on past and current research efforts.

The findings were released on 12th April 2019 in a white paper, [Central Banks and Distributed Ledger Technology: How are Central Banks Exploring Blockchain Today?](#)

Ashley Lannquist, Blockchain Project Lead at the World Economic Forum says: “As the blockchain hype cools, we are starting to see the real use cases for blockchain technology take the spotlight.

“Central bank activities with blockchain and distributed ledger technology are not always well known or communicated. As a result, there is much speculation and misunderstanding about objectives and the state of research. Dozens of central banks around the world are actively investigating whether blockchain can help solve long-standing challenges such as banking and payments system efficiency, payments security and resilience, as well as financial inclusion.”

It is not widely known, for instance, that the Bank of France has fully replaced its centralised process for the provisioning and sharing of SEPA Credit Identifiers (SCIs) with a decentralised, blockchain-based solution. SEPA, or Single Euro Payments Area, is a payment scheme created by the European Union and managed

on a country-by-country basis for facilitating efficient and secure cross-border retail debit and card payments across European countries.

The solution is a private deployment of the Ethereum blockchain network and has been in use since December 2017. It has enabled greater time efficiency, process auditability and disaster recovery. [The fact that dozens of central banks are exploring](#) and in some cases implementing, blockchain technology is significant, according to the white paper. It is an early indicator of the potential use of this emerging technology across financial and monetary systems.

“Central banks play one of the most critical roles in the global economy and their decisions about implementing distributed ledger and digital currency technologies in the future can have far-reaching implications for economies,” Lannquist says.

## Top 10 central bank use cases

Following interviews and analysis, how central banks are experimenting with blockchain can be highlighted by 10 top use cases.

### 1. Retail central bank digital currency (CBDC)

A substitute or complement for cash and an alternative to traditional bank deposits. A central-bank-issued digital currency can be operated and settled in a peer-to-peer and decentralised manner, widely available for consumer use. Central banks from several countries are experimenting, including those from the Eastern Caribbean, Sweden, Uruguay, the Bahamas and Cambodia.

### 2. Wholesale central bank digital currency (CBDC)

This kind of digital currency would only be available for



commercial banks and clearing houses to use the wholesale interbank market. Central bank-issued digital currency would be operated and settled in a peer-to-peer and decentralised manner. Central banks from several countries are experimenting, including those from South Africa, Canada, Japan, Thailand, Saudi Arabia, Singapore and Cambodia.

### **3. Interbank securities settlement**

A focused application of blockchain technology, sometimes involving CBDC, enabling the rapid interbank clearing and settlement of securities for cash. This can achieve “delivery versus payment” interbank systems where two parties trading an asset, such as security for cash, can conduct the payment for and delivery of the asset simultaneously. Central banks exploring this include the Bank of Japan, Monetary Authority of Singapore, Bank of England and Bank of Canada.

### **4. Payment system resiliency and contingency**

The use of distributed ledger technology in a primary or back-up domestic interbank payment and settlement system to provide safety and continuity in case of threats, including technical or network failure, natural disaster, cybercrime and others. Often, this use case is coupled with others as part of the set of benefits that a distributed ledger technology implementation could potentially offer. Central banks exploring this include the Central Bank of Brazil and Eastern Caribbean Central Bank.

### **5. Bond issuance and lifecycle management**

The use of distributed ledger technology in the bond auction, issuance or other life-cycle processes to reduce costs and increase efficiency. This may be applied to bonds issued and managed by sovereign



states, international organisations or government agencies. Central banks or government regulators could be “observer nodes” to monitor activity where relevant. Early implementation is being conducted by the World Bank with their 2018 “bond-i” project.

## 6. Know-your-customer (KYC) and anti-money-laundering (AML)

Digital KYC/AML processes that leverage distributed ledger technology to track and share relevant customer payment and identity information to streamline processes. This may connect to a digital national identity platform or plug into pre-existing e-KYC or AML systems. Central banks exploring this include the Hong Kong Monetary Authority.

## 7. Information exchange and data sharing

The use of distributed or decentralised databases to create alternative systems for information and data sharing between or within related government or private sector institutions. Central banks exploring include the Central Bank of Brazil.

## 8. Trade finance

The employment of a decentralised database and functionality to enable faster, more efficient and more inclusive trade financing. Improves on today's trade finance processes, which are often paper-based, labour-intensive and time-intensive. Customer information and transaction histories are shared between participants in the decentralised database while maintaining privacy and confidentiality where needed. Central banks exploring this include the Hong Kong Monetary Authority.

## 9. Cash money supply chain

The use of distributed ledger technology for issuing, tracking and managing the delivery and movement of cash from production facilities to the central bank and commercial bank branches; could include the ordering, depositing or movement of funds and could simplify regulatory reporting. Central banks exploring this include the Eastern Caribbean Central Bank.

## 10. Customer SEPA Creditor Identifier (SCI) provisioning

Blockchain-based decentralised sharing repository for SEPA credit identifiers managed by the central bank

and commercial banks in the SEPA debiting scheme. This is a faster, streamlined and decentralised system for identity provisioning and sharing. It can replace pre-existing manual and centralised processes that are time- and resource-intensive, as seen in the Bank of France's Project MADRE implementation.

## Emerging economies may benefit most: Cambodia, Thailand and South Africa and others experimenting

The National Bank of Cambodia will be one of the first countries to deploy blockchain technology in its national payments system for use by consumers and commercial banks. It is implementing blockchain technology in the second half of 2019 as an experiment to support financial inclusion and greater banking system efficiency.

The Bank of Thailand and the South African Reserve Bank, among others, are experimenting with CBDC in large-scale pilots for interbank payment and settlement efficiency. The Eastern Caribbean Central Bank is exploring the suitability of distributed ledger technology (DLT) to advance multiple goals, from financial inclusion and payments efficiency to payment system resilience against storms and hurricanes.

“Over the next four years, we should expect to see many central banks decide whether they will use blockchain and distributed ledger technologies to improve their processes and economic welfare,” Lannquist said. “Given the systemic importance of central bank processes and the relative freshness of blockchain technology, banks must carefully consider all known and unknown risks to implementation.” ■

**Ashley Lannquist**

**Project Lead, Blockchain and Distributed Ledger Technology**

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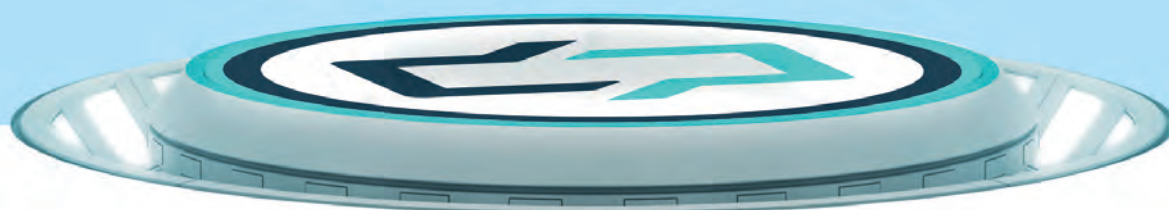
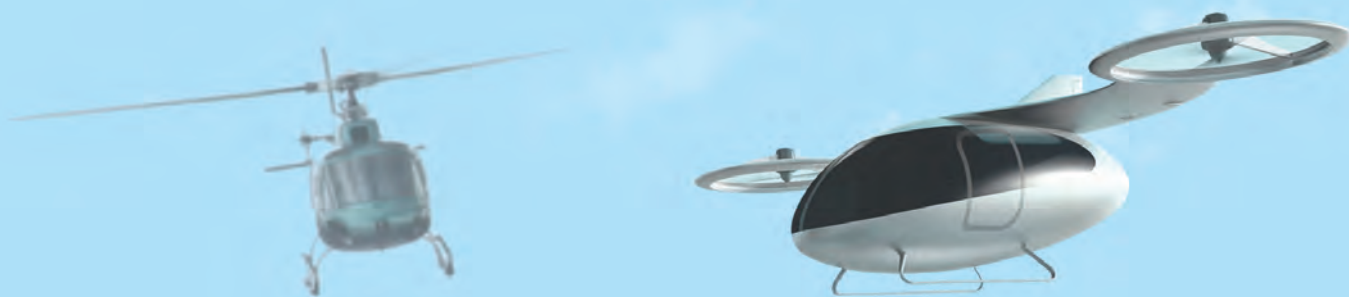


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# Filling the gap between traditional banking and crypto

Whilst some people still 'trust' traditional financial institutions, many people are looking for a new world of banking including crypto, HEDpAY explores here

Unlike traditional money, crypto is decentralised, meaning it is outside the control of governments and banks. The banks have therefore largely shunned crypto, which has also come under increasing scrutiny from regulators.

Traditional banks are seeing the potential value of crypto but bringing them together requires restructuring of legacy systems, adaption to the desires of the new consumer generation and changes to rules and regulations.

"HEDpAY is one of the first projects connecting traditional bank and the crypto universe," says Vicken Kaprelian, HEDpAY Founder and CEO.

HEDpAY formed a structural platform completing full e-banking and e-commerce cycle combining fiat currencies and crypto coins/tokens providing banking system POS and ATM possibilities to merchants and businesses, HEDpAY grouped and partnered with major firms in ASIA to maximise adoption and cross border activities.

HEDpAY expansion on exchanges gives the opportunity to users to have the best choice of crypto to fiat currency conversion, that helps merchants to minimise their cost.

Blockchain transactions and experience with banks are expanding on a very fast pace, after institutions

validating the useful technologies in blockchain and the crypto market, HEDpAY being pioneer in its solution concept, will present banking instruments for medium and long term investments on traditional stock exchanges and crypto exchanges combined, that will be a decentralised form of open ledger on blockchain.

HEDpAY's CEO Vicken Kaprelian, comments on institutional instruments stating that: "Medium-term notes and long-term notes or tokens will be the trend for the upcoming crypto market after the term of "stablecoin" settling in year 2018-2019 and using the formality of "equity token" or "security token", the well performing companies on the market will have the better rating on their "notes/tokens" this is what the future waits and being prepared for on HEDpAY platform on the institutional business side of it."

Traditional day to day activities like peer to peer transactions or sales, even trade on exchanges will be simple, fast and almost cost free, whereas the bigger business will be same way acting faster and transacting faster with minimum cost, almost free to the ratio of traditional fees, HEDpAY goal with its alliances and partners is to minimise expenses and maximise adoption on businesses and living standards of the mass by using both traditional banking and crypto, suiting each in its useful place of activity on one platform.

HEDpAY's business plan for crypto companies and its alliances in Asia, will become the solution platform that companies use as a payment fintech Fiat and crypto platform. It will probably be one of the biggest platforms in South Korea. About 30+ companies will join into the POS, ATM and Vending Machine platform. It will be the first Korean token business to be used in real life, already agreements and contracts are in place with HEDpAY Ltd.

HEDpAY additional activities towards the communities and the young generations, is supporting them with their education, by creating a system to give equal chance to all globally, to have full education by using LIKERWORLD and the Tokens devoted for it at HEDpAY platform, variety of packages will be presented to special needy regions.



## HEDPAY

HEDpAY Limited  
27-28 EastCastle Street, London, W1W  
Tel: +44 (0)209 8123 0060  
info@hedpay.com  
www.hedpay.com

# Strengthening a proactive fiscal policy in China

This article provides insight into the work of China's Minister of Finance Liu Kun, who is responsible for strengthening a proactive fiscal policy in one of the world's biggest and most powerful economies

China's Minister of Finance Liu Kun is responsible for strengthening a proactive fiscal policy in one of the world's biggest and most powerful economies.

Since China introduced reforms in the late 1970s to create a "socialist market economy", known in the West as the Opening of China, the country has consistently had one of the world's fastest-growing economies.

This has brought about huge changes, both economic and social, including the rapid growth of the private sector, a rise in foreign investment and burgeoning demand for consumer goods. Indeed, China is the world's largest manufacturer and exporter, the second-biggest importer of goods and the fastest-growing consumer market.

Average incomes have risen, though so too have income disparities, while China's unequal transportation system and differences in human and natural resources have produced significant variations in regional economies.

President Xi Jinping's "Chinese Dream" has the dual goals of achieving the "Two 100s": firstly, China becoming a "moderately well-off society" by 2021, the 100th anniversary of the foundation of the Communist Party; and secondly, for China to become a fully developed nation by 2049, the 100th anniversary of the founding of the People's Republic.

Liu Kun has been China's Minister of Finance since March 2018. He oversees the formulation and implementation of fiscal and taxation strategies, policies for macroeconomic regulation and control, international negotiations on finances and debt and central government's fiscal revenue and expenditure management.

As party secretary of the Ministry of Finance, he is in charge of the Department of Taxation, the Department of Budget, the Department of Defence and the Department of Personnel & Education.

A key priority for the Ministry, as mandated by the Central Economic Work Conference held at the end of 2018, is strengthening and improving the implementation of a proactive fiscal policy.

In a recent speech, Liu Kun said that: "from the perspective of building a well-off society in an all-round way, it is necessary to support the fiscal policy to consolidate China's economic stability and progress."

"In recent years, we have paid great attention to the advantages of the fiscal policy control structure and adhered to the supply-side structural reform as the main line and achieved remarkable results," he adds.

"At the same time, we must also see that China's supply system is still not adapting to changes in the demand structure and it is difficult for the economy to achieve a virtuous circle.

"Implementing a proactive fiscal policy and intensifying efficiency, while stabilising aggregate demand, increasing support for supply-side structural reforms, promoting the resolution of deep-seated structural problems in economic development, is conducive to enhancing the quality advantages of China's economy."

The Minister acknowledged that the real economy faces many difficulties and risks in key areas, as well as relatively large downward pressure.

"To consolidate China's overall economic stability and steady progress, it is necessary to continue to imple-



“Since China introduced reforms in the late 1970s to create a “socialist market economy”, known in the West as the Opening of China, the country has consistently had one of the world’s fastest-growing economies.”

ment a proactive fiscal policy and increase efforts to improve efficiency, stabilise employment, stabilise finance, stabilise foreign trade, stabilise foreign investment, stabilise investment and stabilise expectations.”

Tax reduction and fee reduction are seen as key measures to deal with the downward pressure on the economy, the Minister said, as it reduces the burden on enterprises, stimulates SMEs and promotes industrial transformation and innovation.

2019 has seen a focus on tax cuts set out in a “big gift package” to the people. This includes a reduction in corporate tax and social security contributions worth nearly 2 trillion yuan, described as the “largest tax reduction in history.”

There has been a reduction in VAT for industries such as manufacturing from 16% to 13% and from 10% to 9% for sectors including construction and transportation.

In addition, since 1st January, small and micro-enterprises with monthly sales of less than 100,000 yuan have been exempted from value-added tax.

Furthermore, since the start of this year, six special deduction policies for personal income tax related to children’s education and continuing education have benefited around 48.8 million people. Overall, 91.6 million people do not have to pay any personal income tax.

Another key element of achieving a well-off society is fighting the “three major battles” of supporting technological innovation, supply-side reform and rural development.

“The financial sector plays a particularly important role in supporting the three major battles,” Liu Kun says.

“By grasping the most direct and most realistic interests of the people, highlighting the publicity and fairness of finance and improving the fiscal and taxation arrangements, we can effectively play the role of preventing and defusing major risks, eliminating poverty and improving the quality of the ecological environment.”

Nevertheless, China’s efforts to improve the implementation of a proactive fiscal policy have brought enormous pressure on the fiscal balance. In order to make up the resource gap caused by large-scale tax and fee reductions, the central government has reduced general expenditures and arranged for local transfer payments to exceed 7.5 trillion yuan, the largest seen in recent years.

In the face of these fiscal reductions, it is up to government at all levels to “take the lead in tightening their lives”, the Minister said, to ensure annual budgets balance and policies are implemented.

“Always adhere to hard work, diligence and saving,” he adds.

“We must take the tight days as the long-term policy of financial work and implement and reflect them in the whole process and all aspects of financial work.” ■

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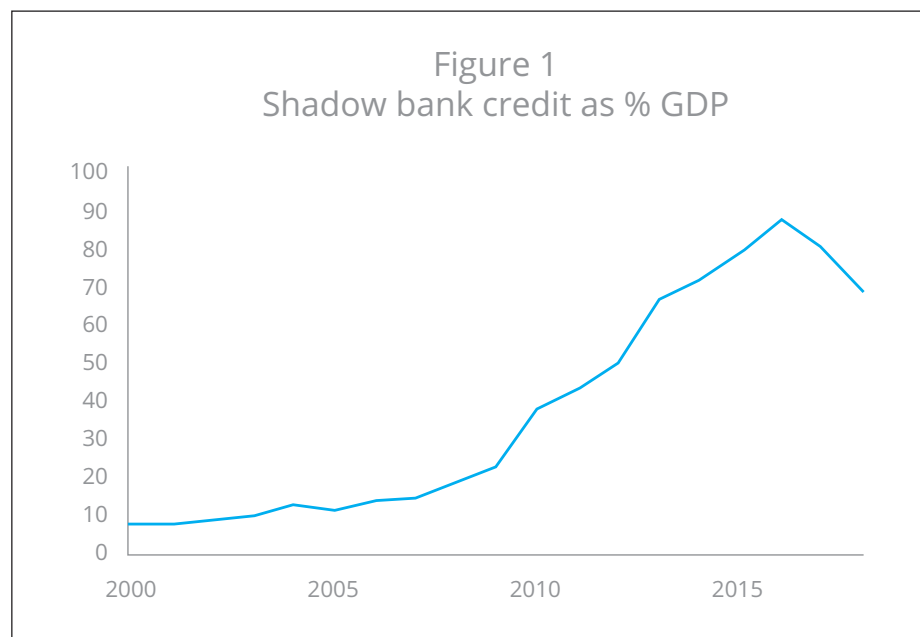
# Chinese shadow banks: Threat or opportunity?

Kent Matthews, Cardiff University and Zhiguo Xiao, Fudan University, discusses whether new Chinese shadow banks are a threat or an opportunity

Chinese shadow banking has come in for a lot of bad press in recent years. The threat of being the cause of financial instability has resulted in the regulatory authorities clamping down on its activities. Our research suggests that this type of regulation can do more harm than good and does little to reduce the potential of financial instability. We argue that a credible Friedman-type monetary rule, price-level targeting, or nominal income targeting policy is more effective in reducing the likelihood of financial instability than heavy-handed regulation.

Shadow banking (SB) relates to all financial services provided by uninsured and unregulated financial institutions. While registered commercial banks and financial institutions must abide by certain rules to protect investors, depositors and borrowers, the shadow banking sector flies under the regulatory radar. Shadow banking in China is distinguished from its Western counterpart in two ways. First, it is much less complex.

Basically, shadow banks are engaged in providing credit that otherwise would have been provided by the regulated commercial banks. Second, it is much more integrated into the regular banking system than in the West. In China, shadow banking has grown enormously over recent years as a result of regulatory and political factors that stem from the reluctance of



state-owned banks (SOBs) to provide loans to small to medium-sized enterprises (SMEs), and an ongoing need by provincial government to access funds for infrastructure projects.

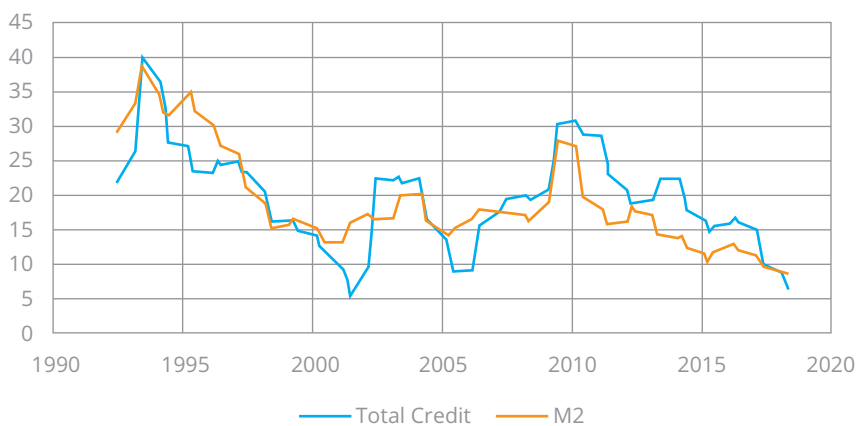
In 2000, SB accounted for less than 10% of China's economy. It grew rapidly following the Global Financial Crisis (GFC) in 2008/9 and reached a peak in 2016 at over 80% of gross domestic product (GDP). In recent years it has fallen due to increased regulatory pressure (Figure 1).

At first, the growth in SB was tolerated by the authorities as a way of meeting the funding needs of private enterprises and SMEs. However, because of its rapid growth and increase in debt, the SBs have come under stricter regulatory pressure from the authorities,

resulting in the closure of thousands of P2P platforms and unprecedented defaults of corporate bonds. The policy of deleveraging the Chinese economy along with a few high-profile fraud activities in the SB sector has prompted the Chinese regulatory authorities to raise the regulatory burden on shadow banks and to squeeze them out of the non-bank financial intermediation business.

Shadow banking has always existed in China in the form of pawn shop lending and rural credit cooperatives, but these entities were too small to pose any threat to the formal financial sector. As Figure 1 shows, the explosion in growth came after the Chinese government stimulus package of RMB four trillion following the onset of the GFC. The fiscal component of the

Figure 2  
4 quarter moving average % growth



stimulus package was relatively small, and the bulk of the stimulus came in the form of bank loans. Bank credit exploded and in 2009 was growing at the annual rate of 35%.

**“The threat of being the cause of financial instability has resulted in the regulatory authorities clamping down on its activities. Our research suggests that this type of regulation can do more harm than good and does little to reduce the potential of financial instability.”**

Much of this credit explosion was directed towards property development and infrastructure spending by local governments. To meet the credit growth ordained by state policy the commercial banks increased their use of off-balance sheet methods such as wealth management products. This is a type of liability management that enabled the increase in funding by avoiding the normal deposit route because of government controls on deposit rates and also for avoiding costly capital charges.

Much of shadow bank lending is also done through state run organisations. SOBs have been the main supplier of

wealth management products and State-owned enterprises (SOEs) have on-lent excess liquidity available to them at preferential rates to SMEs and other private enterprises. This highlights the inter-connectedness of shadow banking in China with the formal commercial banking system.

Furthermore, since these SB entities are not deposit taking institutions, they hold their funds in licensed banks as commercial deposits. Hence SBs are not liquidity creators – they do not increase liquidity, but they are liquidity distributors. The difference between the lending by the regular banks and the SBs is that the latter are lending to more risky ventures. Figure 2 shows the rate of growth of total credit, which is the sum of bank credit and SB credit. The differences in growth rates are due to double counting as not all SB funding is from off-balance sheet vehicles as some direct lending by the banks to SOEs are on-lent to SMEs.

The rapid growth of credit alarmed the authorities who saw this as uncontrolled leveraging that will create greater fragility in the economy. Their

reaction has been to introduce extra controls on the growth of shadow banking which has slowed its continued growth. But the danger of excessive regulation is that it could do more damage than intended and end up harming the positive outcomes that follow the development of shadow banking.

Our research is distinguished by its methodology which employs the method of indirect inference to estimate and test a macroeconomic model as opposed to the popular Bayesian method. It shows that increased controls cause distortions to the economy that inhibit the growth of the productive SME sector, and doesn't necessarily reduce the potential of financial instability. We find that credible and well-designed monetary policy reduces the likelihood of financial instability without the need for heavy-handed regulation that distorts the efficiency of the banking system.

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**Kent Matthews**  
**Professor of Banking and Finance**  
 Cardiff Business School  
 Tel: +44 (0)292 087 5855  
 matthewsk@cardiff.ac.uk  
<https://www.cardiff.ac.uk/people/view/609509-matthews-kent>

# Taxation and consumption:

## The reaction of consumers to an unanticipated tax change

In this second article in a mini-series of three articles highlighting recent macroeconomic research on the effects of taxation on the economy, Bernd Hayo, Professor at the University of Marburg discusses the reaction of consumers to an unanticipated tax change ([read the first article here](#))

Fiscal policy, the increase and decrease of either government expenditure or taxes, is an important macroeconomic stabilisation instrument. Increasing taxes is assumed to decrease consumer spending, with the reverse response expected for decreasing taxes. Economic research on the effects of tax changes tends to use theoretical models or statistical estimations, which often suffer from assuming non-realistic consumer responses or weak identification of the policy change. Following related research on the U.S. (see, e.g. Shapiro and Slemrod 1995); Hayo and Uhl (2017) employ a different approach by directly asking consumers about their behaviour to more accurately investigate the real-world consequences of increased taxation.

In Germany, private final consumption expenditure accounts for approximately 60% of gross domestic product (GDP), suggesting that consumption responses are highly relevant when analysing the macroeconomic consequences of tax changes. Consumption responses to tax changes represent an important feature of public debate about the effectiveness of fiscal stimulus but are also the core of the transmission of fiscal policy shocks in most macroeconomic models. Under-

standing responses to tax changes in Germany are, therefore, important for both economic policy and academic research.

Statutory pension insurance in Germany is a pay-as-you-go system, where current contributions are used to pay for current pensions. The pension insurance contribution rate is divided between employers and employees. It is financed by a proportionate tax on monthly income. Future pension entitlements depend on the income of the insured but not on the contribution rate. At the beginning of 2013, about two months before the survey was conducted, contribution rates to the statutory pension insurance system in Germany were reduced from 19.6 % to 18.9%, thus lessening the overall tax burden of employees and employers. The rate change needed to be implemented because the statutory pension insurance is not allowed to accumulate a substantial surplus, i.e. it can be interpreted as an exogenous German tax shock of average size.

Hayo and Uhl's (2017) research uses a representative survey of the German population, with the analysis focusing on those respondents contributing to the statutory pension insurance system. When asking respondents

about whether they planned to save or spend the additional household income received from the tax reduction, 55% stated that they intended to increase spending. These results suggest that taxation can significantly affect consumption.

Hayo and Uhl (2017) also investigate economic and socio-demographic factors associated with consumption. The respondents' perception that the tax change was either temporary or permanent was not a significant explanatory variable at the individual level, suggesting that both types of tax changes have similar effects on consumer behaviour. Expectations of future economic outcomes however were statistically insignificant, indicating that variation in expected income over the business cycle does not alter the impact of tax changes. Factual knowledge of the budget deficit, interest rate and inflation rate data was also not worth considering statistically.

It is interesting to investigate whether economic knowledge is systematically associated with consumption responses to tax changes, as this is a typical assumption made in macroeconomic theory. For instance, intertemporal utility maximisation requires economic agents to know the actual value of real interest rates. Likewise, Ricardian



“Empirical results using survey data suggest that taxation can significantly affect consumption.”



equivalence is based on the idea that rational agents take the government's intertemporal budget constraint into account.

When Hayo and Uhl (2017) analyse factual knowledge, they discover that only 9% of survey respondents were able to correctly identify the previous year's budget deficit, 36% chose the correct long-term interest rate and 66% selected the correct rate of inflation. Judging from these findings, it seems that consumers in Germany are not particularly well-informed about macroeconomic variables that they are assumed to know about in widely-used macroeconomic models. Instead, economic knowledge or 'economic literacy' does not appear to be associated with different consumption behaviour in response to tax changes.

In the survey, individuals who perceived the current return on savings to be low, even if they did not know the actual interest rate level, were much more likely to spend the additional money from the tax change.

This highlights the fact that interest rates are an important determinant of consumption and saving decisions. Such findings are also indicative of the current low level of interest rates resulting in lower savings.

In addition, those with a high level of household income were 14% more likely to increase spending in response to tax changes. The proportion of individuals replying 'mostly spend' was 49% for low-income households, 57% for medium-income households and 60% for high-income households. This contradicts traditional wisdom going back to John Maynard Keynes that low-income households are characterised by a higher marginal propensity to consume.

Finally, individuals that can be defined as 'Ricardian consumers' (here: those who save more when public debt increases) were significantly less likely to spend the additional money. However, using a more sophisticated way of identifying Ricardian consumers, Hayo and Neumeier (2017) demonstrate that this group showing rational

behaviour in the way typically assumed in economic models constitute only a minority of German consumers.

Summarising the discussion, three contributions to the research literature can be identified. First, perceptions of the tax change being temporary or permanent had no significant effect on consumption. Second, the evidence is provided that individuals, who perceive the attractiveness of saving to be low, have a higher propensity to spend. Third, households with higher income actually appear to have a higher propensity to consume than lower income household after controlling for other factors, which stands in sharp contrast to conventional wisdom.

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[Read the first article here](#)



**Bernd Hayo**  
**Professor**

University of Marburg

Tel: +49 (0)6421 282 3091

hayo@wiwi.uni-marburg.de

[www.uni-marburg.de/en/fb02/research-groups/economics/macroeconomics](http://www.uni-marburg.de/en/fb02/research-groups/economics/macroeconomics)



# Enabling and promoting economic research in Switzerland

The aims of the Society of Economics and Statistics in Switzerland are discussed here, which includes enabling and promoting economic research and encouraging the work of young economists

**T**he Swiss Society of Economics and Statistics (SSES) aims to enable and promote economic research in Switzerland, including the work done between domestic and international research communities. They notably focus on the work of young economists by providing an appropriate platform for them to further their careers.

Their publication, the Swiss Journal of Economics and Statistics (SJES) was founded in 1867. This journal is peer-reviewed, publishing theoretical and empirical contributions to any field of economics and attaining an international audience. It is fully financed by the SSES, which enables it to give a platform to early career

economists. It is published quarterly and remains open access, to further enable exposure for the ideas contained within it.

The SSES meets annually, during which time, a financial reward is given to the best economic paper from only authors that are less than 33 years old. This tradition has been in place since 2007, with the latest winners of the SSES Young Economist Award being Andrea Camilli, with the paper "Labour market institutions and homeownership" and Helge Leibert and Beatrice Mäder for the paper "Health care supply and infant mortality: Semiparametric evidence from Germany, 1928-1936". They won approximately £1,600 for their



Monika Bütler, the author, says that: “Economists are a fortunate crowd, as is clear from Aymo Brunetti’s contribution: They can rely (not without limits) on the power of the price mechanism, following Adam Smith’s “Invisible Hand”. None of the other social sciences seems to benefit from a similar source of rather robust first approximations.

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**“There are many examples where economic reasoning has indeed led to accurate predictions and useful policy measures. Others – such as some crisis in the Euro Area – occurred because economists ignored what they knew, or because they were ignored by politicians.”**

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“Of course, as any paradigm, it is open for ideological contamination. Yet, few would reject the view that the price mechanism can help to tackle many of today’s challenges like climate change, congestion and demographic change.”<sup>2</sup>

She goes on to positively elaborate on the impact of economists in modern policy: “There are many examples where economic reasoning has indeed led to accurate predictions and useful policy measures. Others – such as some crisis in the Euro Area – occurred because economists ignored what they knew, or because they were ignored by politicians.

“Marion Fourcade comes to the most powerful (and flattering) aid of economists: a counterfactual usually does not exist (especially in macroeconomics). We cannot know what would have happened if economists had not offered their advice.”<sup>3</sup> ■

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work, alongside the recognition and exposure in a field which is often saturated with the work of those who have been economists for decades.

Every SSES annual meeting has a theme: in 2017, this was “Economists and Policy Making”, which interrogated the purpose of economics. The SSES reflected on recent failures by economics to “revive stagnant economies and boost middle-class incomes,”<sup>1</sup> which remains a concern two years later in 2019. The SSES particularly interrogated the access economists working for government agencies, central banks or academic institutions as advisors to policy-makers – they asked, how influential are economists really? What level of influence is morally correct and how do good economists navigate ‘bad’ politics?

The SSES works on figuring out questions like these which are relevant throughout the profession of economics, whether academic or more policy-based. The keynote speech at a SSES conference published in the SSES in 2018, entitled “Economists: moral realists or real moralists? Comment on Fourcade and Brunetti”. Bütler delves into these questions, interrogating classic philosophies of the function of economics.



# Financial risk forecasting in the era of big data: The role of investors' sentiment and attention

Francesco Audrino, Professor of Statistics at University of St. Gallen explains financial risk forecasting in the era of big data and underlines the role of investors' sentiment and attention

**F**inancial markets are a central component of today's economic systems. They not only facilitate the financing of companies but also provide investment opportunities for individual investors, pension funds and insurance companies. Consequently, models producing accurate future financial scenarios are central ingredients for private and institutional investors, economists, business leaders and policymakers to form realistic opinions about what could come next, how to eventually impact it and to be ready to react to it.

As the 2008 global financial crisis clearly showed, classical models estimated on standard economic and financial data were not fully satisfactory. One of the main problems they suffer is that they are not generally able to incorporate the psychological over- or under-reactions of financial investors to particular events and announcements. In fact, regardless of the investors' nature or background, stock market participants make predictions about future developments of stock prices and other investment opportunities that could be influenced by their mood and/or incoherent expectations. Neglecting these collective emotional behaviours could strongly bias the predictions of the models and lead to disastrous consequences such as individual investors'

and companies' bankruptcies and even system-wide financial crises.

For many years, researchers argued that the formation of an investor's prediction is purely based on a rational analysis of a company's revenues, products or more general global trends. Today, however, we know that market participants' decisions are often influenced by their mood. Investors, for instance, have a tendency to interpret and search for information and news that confirm their beliefs or to align their expectations to those of other investors. The irrational behaviour of individuals has been shown to influence financial markets, especially during a crisis.

The proliferation of the internet and social media platforms has created a huge amount of new data that potentially encloses information about people's mood ("sentiment"), beliefs, hopes and fears. For example, after a company publishes its quarterly earnings, we can expect to find related comments and reactions in messages posted on social media platforms. It is, therefore, a natural step to include such variables into the different financial models to try to take advantage of relevant information about possible emotional investors' reactions and to improve the accuracy of the obtained financial predictions.

One of the most important financial variables that investors focus on is the level of risk related to a given financial transaction or investment. In particular, volatility, the variation of the price of financial investment in a given time period, is generally interpreted as the risk of the investment. Although volatilities are inherently unobservable, accurate estimates can be obtained by exploiting the information included in the almost continuous flow of recorded financial transactions. Given the key relevance of volatility in almost all financial applications like portfolio selection or risk management, it is not surprising that many academic researchers during the last few decades focused on introducing accurate ways of understanding and predicting volatility's time-varying behaviour. The question that remains unanswered is whether the recent availability of data coming from social media and from online users' web queries could help improving actual predicting tools.

In the recently started SentiVol project, we try to give an answer to this question by analysing the impact of investors' sentiment and investors' attention on volatility's time-varying dynamics.

As illustrated in figure 1, to perform such an analysis there are a couple of

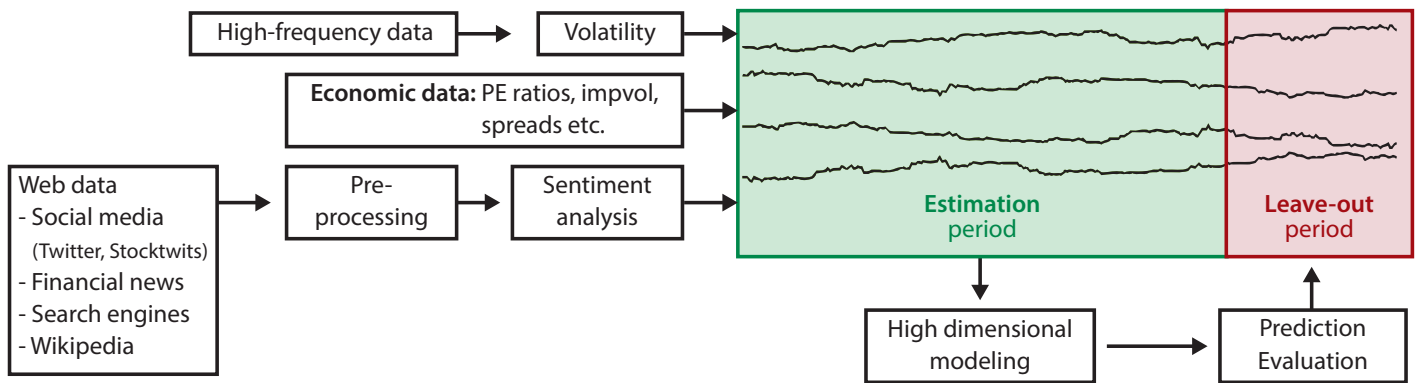


Figure 1.

practical problems that have to be carefully addressed. First, working with such a huge amount of heterogeneous data (that is, high-frequency transaction data and different sources of web data, such as social media messages, news articles or search engine web queries) is not an easy task from both a computational and a modelling point of view. We overcome these challenges by using high computing power and memory, for example, using cloud computing and applying specific high dimensional modelling techniques coming from computational statistics. Second, the nature of social media and web queries data makes pre-processing of the data necessary to incorporate the information they contain in a forecasting model. This includes, for instance, the determination of sentiments from textual data. The latter can be efficiently performed using sophisticated machine learning techniques, such as deep learning methods.

Using this big data set, we constructed several variables, such as the daily average sentiment of investors or the total number of daily messages posted on social media platforms

about a company or the stock market in general for the period from 2012 to 2016. In a first empirical analysis, we investigated the volatility forecasting improvements achieved by a model exploiting our novel dataset for a selection of U.S. companies and the U.S. stock market index. The results showed that measures of sentiment and investors' activity improve the predictive accuracy of future volatility, even when controlling for a wide range of economic and financial indicators. In particular, we found that a high volume of messages posted on the social media platform StockTwits or an increasing amount of web search queries is an early signal of potential stock market volatility peaks. This effect usually lasts one or two days but is particularly strong during periods of market turbulence.

Following our initial findings, our research team currently analyses whether there exist particular channels through which investors' opinion, mood and activity on the web influence financial prices and volatilities and which type of events and news are mostly related with investors' emotional reactions. The hope is that

the inclusion of sentiment and attention variables in volatility forecasting will lead to a better understanding of the way risks related to financial investments behave. This could be a crucial step to anticipate high volatility phases and potentially reduce the effects of the next crash.



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University of St. Gallen

**Francesco Audrino**  
**Professor of Statistics**

University of St. Gallen

Tel: +41 71 224 24 31

[francesco.audrino@unisg.ch](mailto:francesco.audrino@unisg.ch)

[https://www.alexandria.unisg.ch/persons/Francesco\\_Audrino](https://www.alexandria.unisg.ch/persons/Francesco_Audrino)

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# Apprenticeships: A high-quality route to skilled employment

The Rt Hon Anne Milton MP, Minister of State for Apprenticeships and Skills at the Department for Education details why apprenticeships are a high-quality route to skilled employment

It never ceases to amaze me just how much energy and enthusiasm there is for apprenticeships – from employers, training providers and, most importantly, from the apprentices themselves.

Apprenticeships offer people of all ages and backgrounds a high-quality route to skilled employment with the option to train at every level in a range of exciting professions like aerospace engineering, cyber security, teaching, law, nursing and fashion.

We overhauled the apprenticeships system two years ago and we have made some great progress. Apprenticeships are now longer, higher-quality and with more off-the-job training. Apprenticeships also provide a proper assessment at the end, with the Levy giving employers more control to invest in the people and skills they need for the future.

We worked with employers to design the new system because it is employers and not government who are best placed to decide what skills apprentices need for their businesses. More and more businesses and employers, for example, Channel 4, Royal Mail, North West Ambulance Trust and Pizza Express are providing people with the opportunity to learn new skills and get great jobs.

It is good news that the number of people starting on their apprenticeship has increased by 10% compared to the same point last year and that over 4 million people have started an apprenticeship since May 2010. But outdated attitudes are still putting some people off apprenticeships which means they're missing out on opportunities to get good jobs and higher salaries. We all - government, employers, careers advisors, teachers and parents - have a role to play to make sure people

are aware that an apprenticeship can be a life-changing opportunity.

Our new apprenticeships campaign 'Fire it Up' is helping to challenge these outdated perceptions and raise awareness of the huge variety of options available for people across the country. Our real live apprentice stars are of all ages and backgrounds, from employers including the Royal Opera House, Transport for London and the NHS.

We had a record-breaking National Apprenticeships Week this year, with over 1,000 events taking place across the country. We are also developing a new leader board of top apprenticeship employers – the new rankings will be independently judged and published annually and will rate the Top 100 large apprentice employers as well as the top 50 SMEs.

I am extremely proud of the progress we have made, but there is still more to do. We want to continue to refine the system so employers and apprentices can make the most of the apprentices out there. Visit our new website ([www.apprenticeships.gov.uk](http://www.apprenticeships.gov.uk)); it provides lots of helpful advice and you can find out about all the great apprenticeship opportunities available across the country. ■

**The Rt Hon Anne Milton MP**  
**Minister of State for Apprenticeships and Skills**

Department for Education

Tel: +44 (0)370 000 2288

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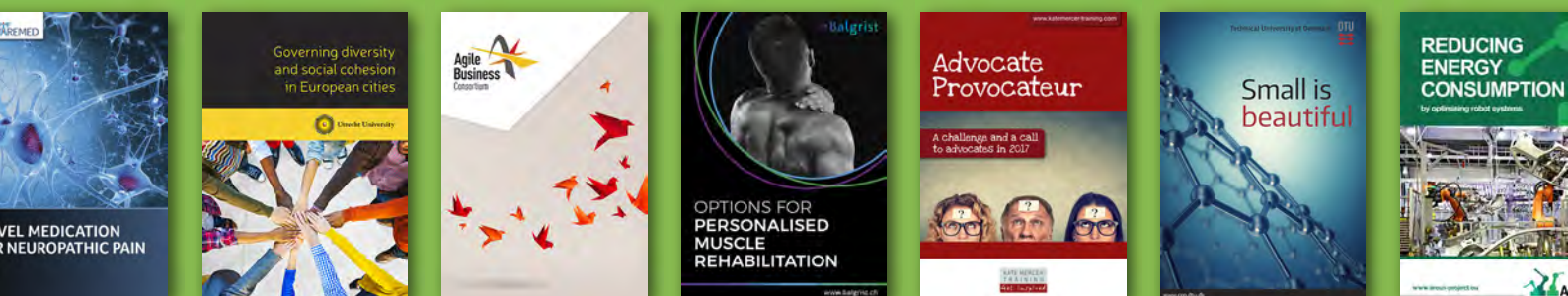
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# Laying the foundations for a successful degree apprenticeship programme

Alasdair Poole, Apprenticeships Manager at Ashridge Executive Education details the importance of laying the foundations for a successful degree apprenticeship programme

**T**he arrival of degree apprenticeships has revolutionised learning for public sector leaders – offering access to Masters-level qualifications that have been out of reach for many during times of austerity.

A growing number of organisations in government and across the health sector are now looking at how they can use their Apprenticeship Levy to fund these high-quality management development programmes, which are designed to build the skills and behaviours executives need to lead their people effectively in challenging times.

So, what are the key advantages of going down a degree apprenticeship route – and what do organisations need to do to set their programmes up for success?

## A pragmatic approach

Ashridge Executive Education is a key player in the degree apprenticeship market and is leading the way with the development of three, highly pragmatic programmes which aim to raise standards of management practice and equip leaders with the agility and resilience needed to succeed in the new world of work.

The Level 6 Degree Apprenticeship is designed to boost the skills and performance of junior and emerging managers, by providing them with the

tools and knowledge to make an immediate difference in the workplace. The three-and-a-half-year programme results in the award of a BA in Business and Management.

There are two Level 7 programmes. The Executive Masters in Leadership and Management is aimed at fast track, middle and established managers who want to stretch themselves using a flexible, self-directed learning approach. The two-year programme covers a range of subjects, from innovation to digital transformation, and places a strong emphasis throughout on personal impact and relational skills.

The more advanced Executive MBA is targeted at experienced managers and functional specialists who want to accelerate their progress into strategic management and leadership roles. This Level 7 qualification is part-funded by the levy, with the employer paying a top-up fee.

The appeal for organisations is the practical, grounded-in-reality approach taken during the programmes. Participants draw on live workplace scenarios as part of their learning, giving them the opportunity to develop fresh perspectives on some of the tough challenges they are facing.

There is also a major, supervised project at the end of programmes, which focuses on an area of organisational

challenge, chosen together with the employer. This not only helps individuals deepen their understanding of the organisation they are working for, but also provides the employer with a valuable piece of internal consultancy it can build on.

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**“On one recent programme, for example, Ashridge actually worked directly with learners to co-create content for a particular module, resulting in a fresh, stimulating learning experience that was directly relevant to the organisation.”**

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Making sure the right foundations are in place is, however, fundamental to the success of any degree apprenticeship programme. Ashridge’s experience in working with organisations going through the first tranche of apprenticeship programmes suggests the following issues are key:

## Senior level endorsement

The employer is an important stakeholder in the degree apprenticeship process, championing participants through their studies and supporting them in applying their new-found knowledge and skills back in the workplace. This means that securing commitment to the programme at the highest level is critical. HR and L&D professionals will need to convince senior management of the potential for degree apprenticeships to help the organisation get future-fit – developing



the skills it will need to thrive in a constantly changing, digitally-driven environment and helping to attract and retain the best talent.

## Clear communication

Misconceptions about apprenticeships still abound and organisations may find they have a certain amount of groundwork to do in explaining how they work at a higher level. A planned internal communications campaign can help to generate enthusiasm and address any concerns that may exist among potential participants. Ideas might include briefings for managers, placing articles on internal communication platforms or drawing up a list of FAQs. Ashridge has supported client organisations by running webinars for potential learners, explaining the degree apprenticeship process and giving participants the opportunity to ask questions.

## Finding the right participants

It's important not to assume that degree apprenticeships will work for everyone. For some individuals, an open programme or being part of a customer group of senior executives can be a better solution. A clear

'recruitment' process will help to ensure the right people are being directed to the right kind of learning. Some organisations have tackled this by inviting expressions of interest from employees, backed up by a short personal statement about why they feel this particular study route will work for them. Offering one-to-one consultations for learners who are undecided or want more information can also be helpful. Ashridge supports organisations with this process, helping them to sift applications if required and advising on alternative options where appropriate.

## Integrating degree apprenticeships

Degree apprenticeships work best when they are seen as part of the bigger L&D picture, rather than a stand-alone development intervention. Organisations need to think strategically about what skills they will need in the future and how a higher level apprenticeship can help to build them. They need to consider what kind of leadership roles will emerge in the new world of work and how degree apprenticeships could prepare employees to fill them. Organisations who take this wider, longer-term view

are more likely to reap the benefits of the programme and get a return on their investment.

## Working in partnership

Finding a provider who fits with the company culture and approach and is willing to develop a close working relationship is critical to the success of a degree apprenticeship programme. A good provider will take a collaborative, consultative approach, working closely with the organisation to design learning that is job specific and immediately transferrable back in the workplace.

On one recent programme, for example, Ashridge actually worked directly with learners to co-create content for a particular module, resulting in a fresh, stimulating learning experience that was directly relevant to the organisation. Finding a provider who is able to be flexible on delivery method is also key, to ensure that managers are able to successfully integrate their studies with demanding day jobs.



**Alasdair Poole**

**Apprenticeships Manager**

Ashridge Executive Education

Tel: +44 (0)1442 841 031

[Alasdair.poole@ashridge.hult.edu](mailto:Alasdair.poole@ashridge.hult.edu)

[www.hult.edu/en/executive-education](http://www.hult.edu/en/executive-education)



# Executive coaching: The hidden benefit

Ross Thompson at Arden University reveals the hidden benefit of executive coaching – which is the potential to unlock talent and capability via the promotion of candour and personal opinion

The growth of the executive coaching industry has been well documented in recent years. Indeed, a recent article in Forbes Magazine <sup>(1)</sup> even suggested that coaching may well be destined to supplant the consultancy industry, with client organisations seeking to “solve” challenges and problems via staff development rather than outsourcing them to a third party. Accounting for the reasons behind this tremendous growth has likewise been well covered in the business press, but there is one key benefit that is frequently overlooked: coaching has the potential to unlock talent and capability via the promotion of candour and personal opinion. The absence of these attributes often bedevils plenary training and development interventions.

Management and leadership development programmes in the 1980s and 1990s tended to be dominated by an abundance of classroom-based training. Delegates were typically treated to a set piece diet of talks, discussions, group working and presentations. Trainers of the day would frequently indicate that the training was interactive and they would incorporate ample opportunities for delegate input and questions. This all sounds good, but it overlooked one key factor: people behave differently in a group context compared to a one-to-one situation. Their candour is frequently inhibited in the former scenario, meaning the level of interaction may be muted.

Academics refer to the “concept validity problem” to describe the phenomenon of failing to capture the precise intention of a research or consultancy question. In other words, a well-conceived and organised study may still generate the wrong answers to the questions. This is because research subjects may interpret the questions in their own way based upon their own context and situation. Something similar can happen

in group training; the mere act of asking for delegate input and comment may not guarantee authentic or comprehensive responses. This is largely because of the group environment itself, which naturally inhibits our desire to be sincere and bare our souls. Honesty is most likely to be restricted if a delegate perceives that an utterance or admission may make them look weak, foolish or inadequate before their colleagues.

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**“A skilled coach can use the privacy and intimacy of a one-to-one environment to build trust, openness and confidence. These are obvious and well-established benefits, but an astute coach will harness them to reduce candour barriers. They will encourage delegates to admit mistakes, concerns and weaknesses enabling the coach to offer the necessary support and guidance.”**

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For example, imagine attending a training event with a selection of colleague managers, all of whom are hungry for career advancement within the organisation concerned. Now, suppose you do not fully understand a key element of the training. Are you going to raise your hand in front of your colleagues (and perhaps superiors – the “gatekeepers” to your career) and ask for clarification or further explanation? Many delegates would not feel comfortable to do so in a situation like this; others might feign agreement and then covertly try to “mug up” on the detail after the event. Outcomes such as these have two major negative consequences. Firstly, the delegate is deprived of the expert clarification from the trainer and secondly, the trainer proceeds under the misapprehension that the key element is fully understood by all delegates.

One-to-one coaching carries with it the potential to eliminate both these problems. A skilled coach can use the privacy and intimacy of a one-to-one environment



to build trust, openness and confidence. These are obvious and well-established benefits, but an astute coach will harness them to reduce candour barriers. They will encourage delegates to admit mistakes, concerns and weaknesses enabling the coach to offer the necessary support and guidance. The delegate is, therefore, no longer prevented from accessing solutions to their concerns, whilst the coach/trainer is able to glean a more accurate assessment of the delegate's needs and tailor or recommend a response accordingly. The "one size fits all" approach, frequently utilised by the group trainers, will struggle to achieve this.

It is not just the supportive "one-to-one" nature of executive coaching that engenders benefits to the coachee. Clever coaches will exploit this relaxed and trusting environment to encourage their coachees to reveal more about themselves, thus paving the way for more

precise and tailored learning and training thus increasing the potential ROI of coaching. ■

1. <https://www.forbes.com/sites/forbescoachescouncil/2018/04/09/15-trends-that-will-redefine-executive-coaching-in-the-next-decade/#7a44c0bd6fc9>

**Ross Thompson**  
**Programme Team Leader – Postgraduate Business**

Arden University  
Tel: +44 (0)20 300 56070  
[contactus@arden.ac.uk](mailto:contactus@arden.ac.uk)  
<https://arden.ac.uk>  
[www.twitter.com/Arden\\_Uni](https://twitter.com/Arden_Uni)

# The unfolding of coaching in organisational life

The unfolding of coaching in organisational life is detailed here by Karen Dean from Diabolo Limited and me:my™coach and Sam Humphrey of Grit Limited

Thirty years ago, there were pockets of executive coaching which were delivered to senior leaders in mostly corporate businesses. In the early stages of such investments being made by organisations, they often targeted people who apparently needed “fixing”. It became increasingly common that some organisations were using coaching as a way of abdicating responsibility for managing performance and not delivering feedback to the prospective client.

**“Team coaching is rapidly moving to the fore as an effective way of developing teams and it is still unclear which specific methodologies are consistently deployed and what standards might be.”**

Coaches came from a variety of backgrounds, philosophies and levels of experience, making it a challenge to demonstrate a return on investment. “Coaching” and “mentoring” were used interchangeably as a defining label. There was then a shift to accelerating high performance which positively impacted how coaching was used and perceived. This brought a risk that the investment seemed to be an elitist benefit. Coaches were often part of the leaders’ network and would be engaged and funded directly by a leader.

Then, movements began to spring up, keen on developing professional stan-



dards in the coaching arena. In 1995, the International Coach Federation (ICF) was founded in the United States to support coaches and the growth of the profession. The first credentials were awarded in 1998. Coach training programmes were accredited shortly afterwards. There are now over 25,000 credential holders worldwide with ICF. Similarly, the European Mentoring and Coaching Council (EMCC) held its inaugural meeting in 2002 and now has 24 affiliated countries. Other bodies also emerged.

As these initiatives took hold, buyers of coaching were becoming more astute and developed criteria for selecting coaching providers. The requirements grew. It is now common to be asked for evidence of accredited coaching qualifications, the number of professional paid hours delivered, the stated coaching philosophy, the

code of ethics, the commitment to continuing professional development and for proof of regular supervision of the coaching practice. As well as types of organisations and contexts in which a coach has worked, preferred supplier lists have flourished in the public sector and registers of appropriately selected coaches now exist. This is significant in the procurement of such services. In education, some school leaders are supported by coaching initiatives. Teaching staff are showing interest in how coaching might offer peer support or impact their approaches with students.

Coaching was still largely in the hands of the external executive coaches and significant investments were made. This was not sustainable as the requirement for an interest in coaching grew. It was an effective method of development which inspired HR



professionals and leaders who had experienced it, to find ways of reaching a broader range of coaching clients. This demanded that coaching initiatives, if successfully deployed, had a vision and that the sponsors of this could describe how that vision was aligned with the strategic plans for the organisation. Funding was more readily available when this was demonstrated.

Groups of internal coach practitioners emerged and HR professionals became more enthusiastic and interested in learning how to coach. The internal coaches delivered coaching as a “job plus coaching” option and they were being trained by accredited organisations. These individuals were able to offer coaching to their peers, supporting them in the workplace. We believe that ethical boundaries and coaching contracts are increasingly important. These ensure that the interventions are safer, remain confidential, do not compromise professional relationships or provoke conflicts and concerns.

Coaching and mentoring deployed as a style of managing has become more prevalent. This has led to descriptions of developing a “coaching culture” in the workplace. The benefits of having one of these are connected to staff retention, staff inclusion, employee satisfaction and improved performance. It has, therefore, become possible to find ways of demonstrating a return on investment which was previously elusive. Behavioural shifts as evidence continue to be relevant.

The Institute of Leadership and Management have developed their offering in training managers and leaders in coaching and mentoring. They cite: “increased confidence, performance and productivity, improved management performance, conflict resolution,

communication and interpersonal skills”. A particularly fine example in “NHS Trust: caring for carers” at Guy’s and St Thomas’ NHS Foundation Trust was described as a case study by Hannah Datema and Bhavet Radia in Volume 14, Issue 3 of Coaching at Work Magazine. This initiative has received at least five awards and great recognition. Much of this programme used technology on an internet-based learning platform with a variety of methodologies plus blended learning opportunities.

Team coaching is rapidly moving to the fore as an effective way of developing teams and it is still unclear which specific methodologies are consistently deployed and what standards might be.

There is still a significant role for external executive coaches to coach key senior leaders. The model published by Humphrey and Marsden in 2010, has the complexity of the coaching agenda as one axis and the level of coach competency required to meet that need, as the other. These illustrate four clear purposes for coaching: “skill”, “performance”, “transition” and “transformation” coaching – all of which can be satisfied by coaches of different skill levels and experience.

Coaches, in our opinion, must strengthen their ways of “being a coach”, as well as the practical “doing” involved in coaching. We explore this in our book, *Coaching Stories: Flowing and Falling of Being a Coach*. We believe coaches must develop a high level of coaching competency. Demonstrating professional commitment to their own growth and management of their coaching practice are both vital.

Karen Dean is an ICF Master Certified Coach with over twenty-five years’ experience in over ninety organisa-

tions. She is the originator of me:my™coach online self-assessment framework for coaches and a coach supervisor.

Sam Humphrey is an accredited coach, supervisor, researcher and author. She has worked in a number of corporate roles prior to becoming a professional coach which she has practiced for nearly two decades.

Karen and Sam’s book: *Coaching Stories: Flowing and Falling of Being a Coach* speaks to managers and leaders who are influencing others as well as internal or external coaches.



**Karen Dean**  
Managing Director, Executive Coach  
and Originator

Diabolo Limited and me:my™coach.

Tel: +44 (0)1158 450 137

Mobile: +44 7802 748 793

karen.dean@diabololimited.com

www.diabololimited.com

www.memycoach.com

www.twitter.com/memybrands

**Sam Humphrey**  
Managing Director

Grit Limited

Tel: +44 (0)7767 417 450

sam@grit.co.uk

# Children and young people with speech, language and communication needs

Taking a system-wide approach for children and young people with speech, language and communication needs in England is the way ahead, argues Chief Executive of the Royal College of Speech and Language Therapists (RCSLT), Kamini Gadhok MBE

**A**s Chief Executive of the Royal College of Speech and Language Therapists (RCSLT), I've lost count of the number of times I've talked to the government about the importance of children's speech, language and communication skills. The evidence is clear: the ability to communicate is a fundamental life skill, directly impacting on children's wellbeing, their learning and their life chances. Without support, children who have difficulties communicating are at high risk of mental health problems, educational underachievement, poor employment prospects and possible involvement in the justice system.

**“...59% of parents of children and young people with speech, language and communication needs said they had to fight to get support for their children's difficulties, and more than half had to wait longer than six months to get it.**

These risks were highlighted in [Bercow: Ten Years On](#), a review of provision for children and young people with speech, language and communication needs in England, published by RCSLT and I CAN in March 2018. The report found that the importance of speech, language and communication skills were widely underestimated, both among the public and decision makers.

So it's been fantastic over the last year to see the Department for Education recognise the crucial importance of early language and communication and announce a number of new initiatives – such as the launch of the Chat, Play, Read campaign to encourage parents to talk to their babies and young children, and their partnership with Public Health England to ensure that children with delayed language or other communication needs are identified early on. This work is in its infancy but has the potential to make a real difference.



Kamini Gadhok MBE

We must not forget, however, that 10% of children and young people – 1.4 million in the UK – have long-term speech, language and communication needs and will need specialist support throughout their childhood and beyond. Our [1st Anniversary Update](#) to Bercow: Ten Years On makes clear that many of these children and young people are still not receiving the support they need. This is due in large part to over-stretched and under-funded speech and language therapy services: over the last few years, many services have been faced with an impossible combination of reducing funding and increasing demand.

It is not only the RCSLT who is saying this: Ofsted and the Care Quality Commission have reported on “unacceptably long waiting times” for therapy services, and the NHS Long Term Plan describes speech and language therapists as a workforce group “in short supply”.

Parents have also voiced their concerns: in a YouGov poll commissioned by the RCSLT and I CAN, 59% of parents of children and young people with speech, language and communication needs said they had to fight to get support for their children’s difficulties, and more than half had to wait longer than six months to get it.

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**“I’ve talked to the government about the importance of children’s speech, language and communication skills. The evidence is clear: the ability to communicate is a fundamental life skill, directly impacting on children’s wellbeing, their learning and their life chances. Without support, children who have difficulties communicating are at high risk of mental health problems, educational underachievement, poor employment prospects and possible involvement in the justice system.”**

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There are some glimmers of hope. We welcome the publication of the NHS Long Term Plan and its ambitions to support prevention, early intervention and tackle health inequality. We were particularly encouraged that the plan recognises speech and language therapy as part of the new models of care which will bring together physical and mental health services for children and young people to provide holistic care which is age appropriate and closer to home. We hope that NHS England will work with us to make this model of care a reality for all children and young people in England. We see the move towards integrated care systems as an opportunity to realise this ambition, through promoting system leadership and improved joint working across health, social care and local authorities.

The announcement of a Leadership Board to clarify and communicate the principles which should under-

pin joint commissioning for children and young people with special educational needs and disability (SEND) is also a positive step. Given the cross-cutting nature of speech, language and communication needs, we are calling for the Board to have this as an explicit focus.

Above all, we need a system-wide approach to children’s communication, underpinned by national leadership. That’s why we’re calling for a cross-government strategy to be developed for children, with speech, language and communication at its core, overseen by a cross-departmental ministerial group. The government has already established a ministerial group for children under-two. They must now take the bold step to extend this approach and give all children and young people the chance to fulfil their potential. ■

For more information about speech, language and communication needs and the role of speech and language therapists, take a look at the [factsheets](#) on the RCSLT website.

**Kamini Gadhok MBE**  
**CEO**

Royal College of Speech and Language Therapists

Tel: +44 (0)20 7378 1200

[www.rcslt.org](http://www.rcslt.org)

[www.twitter.com/RCSLT](https://www.twitter.com/RCSLT)



# The use of artificial intelligence (AI) in education

Dr Elaine Garcia, Senior Programme Leader at InterActive Pro and Edology.com, explores the use of artificial intelligence (AI) in education

The rise of technology within the education sector over the last few decades has been astounding. This is certainly the case if we consider that teaching with technology has become pervasive in almost every classroom environment. Within today's classroom, for example, we find ourselves surrounded by devices such as smart boards, AV, computers, laptops, tablets and phones, to name but a few technologies which are now being integrated into teaching.

We have also seen the rise of the virtual learning environment and blended learning, alongside a significant rise in online education. This has allowed distance learning to take new forms and shapes and to reach greater audiences around the world. Educational technology is now a real part of education and something which, when used effectively, can make a significant impact on teaching and learning.

While it may seem inconceivable to imagine technology not being used within our classrooms today, it is important to note that the road to integrating it was not without its problems. In fact, a number of the technologies which students consider to be core to their studies today were rejected at first by a large number of academics and teachers. They preferred to use more traditional teaching methods and did not want to try something new, different and with which they were not familiar.

A further issue in the introduction of educational technology is that we frequently saw such tools being driven by technologists or IT departments who were pushing to see technology being used persuasively within the classroom, without necessarily considering their pedagogical purposes. In other words, implementing technologies simply for the sake of introducing new technologies.

What we have, therefore, learnt from these experiences is that the pedagogical perspective should drive the introduction of new technology, rather than considering the pedagogical purpose of the technology after it has already been introduced. When technology is introduced without considering its purpose we usually see the replication of traditional forms of teaching and learning using online tools. This is not really sufficient to justify the investment that such technologies will often require.

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**“What is of key importance, however, when considering the use of AI in education, is to once again ensure that it is pedagogy, rather than the technology that is driving the development of new and different approaches to education.”**

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When thinking about introducing new technology, it is important to carefully consider how it can allow learning to take place in new and different ways through different pedagogical perspectives, such as connectivism.

We are now moving into a new age of technology, one in which artificial intelligence (AI) or machine learning are being developed. Therefore, we need to once again consider whether such technology should be used within education and, if it should, how it will be useful in enhancing teaching and learning.

Currently, there are a wide range of predictions of how AI will be integrated into future education. These range from commentators predicting that AI will only take over the administrative tasks of teachers, to others who predict that AI will replace teachers within the classroom entirely. While such concepts may be hard to imagine for the majority of teachers, AI is already being used in some classrooms today. For example, IBM Watson, Third Space Learning and Duolingo Chatbot are all forms of AI already being used to enhance learners' experience.



What is of key importance, however, when considering the use of AI in education, is to once again ensure that it is pedagogy, rather than the technology that is driving the development of new and different approaches to education.

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**“Within today’s classroom, for example, we find ourselves surrounded by devices such as smart boards, AV, computers, laptops, tablets and phones, to name but a few technologies which are now being integrated into teaching.”**

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Certainly, some of the developments discussed so far do appear to focus on what drives teaching and learning. Key issues identified include the manner in which AI can allow greater personalisation and customisation of the educational experience for learners. This, therefore, allows for greater differentiation and individualised learning, both of which are key to teaching and learning.

However, what is yet to be answered is how AI will be able to replicate the empathy and creative thinking that

are a key part of a teacher’s role within the classroom or how the replacement of teachers altogether by AI will be pedagogically advantageous to learning. Before the development of AI for educational use goes too far, this is a vital question that needs to be asked and one which may ensure the implementation of AI within education will be truly advantageous for students of the future. ■

**Dr Elaine Garcia**

**Senior Programme Leader**

Interactive Pro and Edology.com

[www.interactivepro.org.uk](http://www.interactivepro.org.uk)

# Achieving excellence in science, technology, engineering and mathematics education

Here, we examine the mission of the National Science Foundation's Directorate of Education and Human Resources to achieve excellence in science, technology, engineering and mathematics education

Within the National Science Foundation (NSF), the Directorate of Education and Human Resources (EHR) has a clear mission for excellence to be achieved when it comes to supporting science, technology, engineering and mathematics (STEM) education in the U.S. The notion here is that this aim applies at all levels and in all settings so that the development of a well-prepared and diverse workforce of scientists, technicians, engineers, mathematicians and educators are supported.

The goals of EHR can be summarised as follows:

1. To get the next generation of STEM professionals ready and to retain and more Americans for careers in STEM.
2. To encourage a robust research community that can undertake a rigorous evaluation and research that support excellence in STEM education.
3. To increase the scientific, technological and quantitative literacy of everybody in the U.S to help them be responsible citizens and live productive lives in today's technological world.
4. To broaden participation and close achievement gaps in all STEM fields.

Capacity-building strategies of EHR include facilitating the translation of research into practice and creating supportive learning environments and STEM pathways by developing models of reform/systemic change at both institutional and multi-institutional levels through partnerships, networking, alliances and collaborations.<sup>1</sup>

## Graduate Education (DGE)

Under EHR, The Division of Graduate Education (DGE) aims for innovative, inclusive, high-quality graduate

education in the STEM fields. DGE is in charge of innovative cross-Foundation programmes that directly or indirectly support U.S. citizens in their thirst to become the leading engineers and scientists of the future. Certainly, DGE supports research that generates exciting new ideas for graduate education in the years ahead.

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**“The program supports advances in fundamental research on STEM learning and education by fostering efforts to develop foundational knowledge in STEM learning and learning contexts, both formal and informal, from childhood through adulthood, for all groups and from the earliest developmental stages of life through participation in the workforce, resulting in increased public understanding of science and engineering.”**

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An example of their work is the Graduate Research Fellowship Program (GRFP), which directly supports graduate students in the STEM fields and is the oldest federal fellowship program in existence. Another aspect is the NSF Research Traineeship Program (NRT), which sets out to ensure that graduate students in research-based master's and doctoral degree programmes develop the knowledge, skills and competencies required to pursue STEM careers. One final example to look at here is the CyberCorps: Scholarship for Service (SFS) program and one of the aims here is to increase the number of qualified employees working for federal, state, local and tribal governments in cybersecurity.<sup>2</sup>

## Research on Learning in Formal and Informal Settings (DRL)

Also under EHR, Research on Learning in Formal and Informal Settings (DRL) essentially invests in projects to make STEM learning for all people more effective. Promoting innovative research, development and evaluation of learning and teaching across all STEM disciplines by advancing cutting-edge knowledge and



practices in both formal and informal learning settings sums up its mission.

The EHR Core Research (ECR) program of fundamental research in STEM education provides funding in critical research areas that are essential, broad and enduring. On their website, DRL elaborates further about what they do.

“EHR seeks proposals that will help synthesise, build and/or expand research foundations in the following focal areas: STEM learning, STEM learning environments, STEM workforce development and broadening participation in STEM.

“The program supports advances in fundamental research on STEM learning and education by fostering efforts to develop foundational knowledge in STEM learning and learning contexts, both formal and informal, from childhood through adulthood, for all groups and from the earliest developmental stages of life through participation in the workforce, resulting in increased public understanding of science and engineering.”<sup>3</sup>

### STEM achievement gaps

In a major analysis of university faculty and students in STEM, Indiana University social psychologists found out that professors’ beliefs about intelligence play a measurable role in the success of all students, particularly underrepresented minorities taking their first college-level STEM courses.<sup>4</sup>

“In a university-wide sample, we found that all students – and black, Latino and Native American students in particular – earn significantly higher grades in STEM courses when their professors believe intelligence is a malleable quality that can be developed over time, compared to when their professors believe intelligence is a fixed trait that cannot change very much,” says author Elizabeth Canning, at the IU Bloomington College of Arts and Sciences’ Department of Psychological and Brain Sciences.<sup>5</sup>

### The need for more scientists and engineers

Finally, in other news, the need for more scientists and engineers is highlighted as a persistent issue plaguing industries across the U.S. We learn that a number of

initiatives have been created to prioritise STEM in schools to help educators prepare more diverse students and workers for STEM fields. However, these efforts might be falling short when it comes to the representation of people of colour, according to a Researcher at the University of Missouri.<sup>6</sup>

“People buy into these notions that only certain people can access certain spaces and do certain things,” Morton says. “When somebody tells a black woman that her STEM studies are too ambitious, they are inferring that STEM careers are reserved for people who don’t look like her. However, the women I spoke to were very strong-willed despite these challenges and asserted that they would write their own stories and not buy into other people’s narratives.”<sup>7</sup>

### Closing remarks

The aforementioned examples of news from the STEM field take us back to the earlier point about the mission of the NSF achieve nothing but excellence when it comes to supporting STEM education in the U.S. ■

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- 6 [https://www.nsf.gov/news/news\\_summ.jsp?cntn\\_id=297554&org=DRL&from=news](https://www.nsf.gov/news/news_summ.jsp?cntn_id=297554&org=DRL&from=news)
- 7 <https://munews.missouri.edu/news-releases/2018/1211-blackgirlmagic-black-women-in-stem-are-driving-forward-educators-need-to-catch-up/>

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# Interactive-engagement methods in education: Can we teach students to think like scientists while learning science?

Eugenia Etkina, Distinguished Professor of Science Education at Rutgers, The State University of New Jersey argues that interactive-engagement methods lead to better learning gains than traditional transmission-mode methods and discusses fundamental differences between various interactive engagement techniques

In the past 20 years, the educational community has accumulated enough data to say with confidence that interactive engagement methods lead to better student learning gains than traditional transmission-mode methods (Michael, 2006; Freeman et al., 2014). As Mitchell Waldrop (2015) said: “At this point, it is unethical to teach in any other way.” But what is this way? There are many models of interactive engagement methods. One popular approach is the “flipped classroom” (Fulton, 2012) where the students read the textbook (or watch a video with the instructor explaining the material), then come to class and discuss what they read through answering questions posed by the instructor. They often work in pairs and participate in voting for the best answer.

An example of a flipped classroom in physics education is the method of Peer Instruction (Mazur, 1997). While the students in these classrooms work collaboratively answering questions and lecturing is limited, the knowledge that students begin with comes from authority. Students get acquainted with physics concepts by reading the book or watching a video with an authority figure on the screen. While such methods lead to more learning than traditional lecturing,

what message about physics are they sending to the students? One answer is that science is an area of study that can be learned by reading the book and discussing what you read in class. Is this the message we want our students to get from our science classes?

Physics, chemistry, biology are experimental sciences. As the history of physics (Holton & Brush, 2001), the writing of physicists about their work (Born, 1943) and observations of this work in real time (Poklinek Cancula, Planinsic, & Etkina, 2015) show, the origin of every physics idea can be traced to experiments. The same is true for biology and chemistry. Sometimes an anomalous or interesting experimental result made scientists question what they observed. Then they (or somebody else) tried to explain and quantify the observed phenomenon. Multiple hypotheses were tested experimentally and those that were not ruled out remained and are now in the textbooks. When students start learning a concept by reading the textbook, they see the final outcome of this process not knowing where it came from. But maybe they learn where ideas come from by doing experiments in instructional laboratories? Research shows that this is not the case (Holmes, Olson, Thomas, & Wieman, 2017). Traditional labs that

provide step-by-step instructions do not engage students in the development of new concepts, they mostly focus on the “verification of theory”.

But why drag our students through “discoveries” if they can quickly learn the right concept and practice applying it? This seems much more efficient and practical. However, it turns out, that being able to investigate phenomena, to cope with multiple solutions, to evaluate assumptions, to test different ideas are exactly the skills that will make our students successful in the future (OECD, 2018), not using the facts explained to them by somebody else. Future employers will need people who not only have disciplinary knowledge but also epistemic knowledge (how to “think like a mathematician, historian or scientist”) (OECD, 2018, p.5).

But how is it possible to create an environment in which students can “discover” and learn physics for themselves in ways similar to how physicists work—to own it, so to speak, within a reasonable time? An example of such an environment or an interactive method of teaching is the Investigative Science Learning Environment (ISLE) (Etkina & Van Heuvelen, 2007; Etkina, 2015). There are three key features of this approach, detailed below, which mirror the features of a scientific

inquiry while at the same time allowing students to develop traditionally valued physics knowledge (normative concepts).

**1.** Students develop normative physics concepts as their own ideas by repeatedly going through the following steps

(a) Observing pre-selected phenomena (experiments) and looking for patterns;

(b) Developing multiple explanations for these patterns;

(c) Using these explanations to make predictions about the outcomes of testing experiments that they design;

(d) Deciding if the outcomes of the testing experiments match the predictions;

(e) Revising the explanations if necessary, examining assumptions or going back to collect more observational data and;

(f) Applying tested and not ruled out explanations for practical purposes (building devices, determining the values of physical quantities, etc.).

**2.** While engaged in steps (a) – (f) students represent physical processes in multiple ways, developing productive tools for qualitative reasoning and problem-solving.

**3.** While engaged in steps (a) – (f) students work collaboratively in groups of 3-4 using small whiteboards and then share their findings, designs and solutions in a whole class discussion.

Only after all these steps the students read the textbook and compare the ideas that they have constructed on their own with the ideas presented in the book. The combination of these

features applies to every conceptual unit in the ISLE learning system.

While it might seem impossible that the students can learn all of the general physics following the sequence outlined above our experience and the experience of many teachers across the world shows that it is. ISLE was originally developed by E. Etkina and later enriched through collaboration with A. Van Heuvelen, S. Brahmia, D.T. Brookes, G. Planinsic, X. Zou and many others. It is being used in high school and college classrooms and teacher preparation programmes. We developed a plethora of educational materials to help implement this approach, many of which are available on the Internet. In my next editorial, I will show several examples of knowledge construction following the ISLE process and share the resources available.

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**Eugenia Etkina**

**Distinguished Professor of  
Science Education**

Rutgers The State University of New Jersey,  
Graduate School of Education,  
Department of Learning and Teaching  
Tel: +1 831 295 2301

[Eugenia.etkina@gse.rutgers.edu](mailto:Eugenia.etkina@gse.rutgers.edu)

[https://gse.rutgers.edu/eugenia\\_etkina](https://gse.rutgers.edu/eugenia_etkina)

<http://www.islephysics.net/>

<http://www.islephysics.net/pt3/>

<https://sites.google.com/site/scientificabilities/>

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# The DREAM STEM Project at North Carolina Central University: Retaining talent

Caesar R. Jackson, Professor of Physics explores the DREAM STEM Project at North Carolina Central University, which includes retaining science, technology, engineering and mathematics talent in the U.S.

Science, technology, engineering and mathematics (STEM) educated graduates often become substantive contributors to the economic vitality of the nation and reap higher economic benefits during their careers, yet there are persistent challenges in producing and retaining STEM talent in the United States (U.S.) to meet the future science and engineering workforce demands.

As the U.S. population shifts toward an increasingly multiracial society, the current racial/ethnic gap in science degree production from institutions of higher education forecasts a severe shortage of diverse scientific workers. Although about 28% of all U.S. college students select a STEM major, more than half switch to a non-STEM field or leave postsecondary education without earning any credentials. This departure rate is even higher for individuals from groups underrepresented in STEM, including African Americans.

Historically, black colleges and universities (HBCUs) play a significant role in producing African American scientists. HBCUs were established with the deliberate purpose of serving African Americans and these institutions, despite categorically being underfunded and lacking sufficient resources, serve and

are effective in educating more low-income, first-generation students than all other institutions of higher education. Even though HBCUs constitute only 3% of the postsecondary institutions in the U.S., they award 17% of all of STEM baccalaureate degrees earned by African Americans and 24% of the African Americans who earned a doctorate in science and/or engineering received their bachelor's degree from an HBCU.

The U.S. National Science Foundation (NSF), initiated the Historically Black Colleges and Universities Undergraduate Program (HBCU-UP) to assist HBCUs to more fully realise their promise as major contributors to the nation's STEM degree completion goals. The grants awarded from the HBCU-UP are administered by NSF's Division of Human Resource Development within in the Directorate for Education and Human Resources. North Carolina Central University (NCCU), an HBCU located in Durham, North Carolina, was awarded funding from HBCU-UP in 2012 and the DREAM STEM Project was launched at the university.

DREAM STEM – “Driving Research, Entrepreneurship, and Academics through Mastering STEM” – has as major goals, to increase enrolment

and retention in STEM degree programmes at NCCU, to increase persistence and graduation rates in STEM and to produce highly-skilled STEM graduates who can create and innovate. The strategic components of DREAM STEM comprise:

1. Entrepreneurship in science education;
2. Development of students' identity as scientists and;
3. Faculty development through teaching and learning research innovation mini-grants.

The entrepreneurship in science education component stimulates entrepreneurial thinking in science students by exercising their creative design abilities, helping them to actualise their intellectual and knowledge potential and demonstrating how to realise and capitalise on opportunities. Students are guided through the research and development (R&D) portion of the science and engineering entrepreneurship cycle where they conceptualise creative solutions to realistic problems and engage in the hands-on design of their innovations. Development of students' innovation design skills is complemented with entrepreneurial thinking training on

how to carry out market analysis, identify financing sources to fund their product and protect their intellectual property. Students' entrepreneurial training culminates with their presentation of a business pitch and demonstration of their product prototype to a public audience. Students' self-belief increased significantly after participating in DREAM STEM entrepreneurial training and students felt more confident in their ability to apply scientific knowledge to develop products and processes, turn ideas into feasible business opportunities, develop a product plan, conduct market analysis and make strong presentations.

Student's science identity development is thought to derive from three overlapping constructs: performance, competence and recognition. The DREAM STEM Project accentuates students' science identity through earned academic scholarships, honours and awards (Performance); participation in undergraduate research experiences (Competence); and exposure and recognition in attending and presenting their work at national professional meetings (Recognition).

It was observed that DREAM STEM students felt a strong sense of belonging (i.e., fitting in) while feeling honoured and affirmed for being one's distinct self (i.e., standing out) and subsequently they expressed greater STEM identification and demonstrated significantly higher academic performance in STEM degree programmes.

The DREAM STEM Project promotes the scholarship of teaching and learning through mini-grant funding awarded to committed STEM faculty who implemented and assessed new

and promising pedagogical strategies that stimulated students' active engagement in learning science and mathematics subjects. Gains in students' STEM learning were greatest in STEM courses that included active learning approaches in lecture sessions along with guided inquiry approaches in the associated laboratory sessions of the course.

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**“Overall outcomes of the NSF-funded DREAM STEM Project at NCCU include higher enrolment and significantly higher retention, persistence and graduation rates in STEM degree programmes for African Americans students.”**

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In addition, investigation of self-regulated learning behaviours of students in STEM courses at NCCU revealed that self-efficacy for STEM learning & performance had a significant effect on student's effort regulation and self-efficacy was the greatest predictor of the end-of-course grades. Students who exhibited higher academic achievement also exhibited higher self-efficacy, higher effort regulation and higher task value.

Overall outcomes of the NSF-funded DREAM STEM Project at NCCU include higher enrolment and significantly higher retention, persistence and graduation rates in STEM degree programmes for African Americans students. Physics enrolment increased by 82% as a result of a newly created 3-plus-2 dual degree Physics/Engineering program. The first-year retention for DREAM STEM students was 97% compared to 57% for the general STEM population of students. DREAM STEM students persisted in their degree programme to the third year

at a rate of 92% compared to 36% for general STEM population and the five-year graduation rate for DREAM STEM students was 80% compared to 30% for the general STEM population.

As a result of the DREAM STEM Project, average degree production increased in Chemistry by 69%, Mathematics by 50% and Physics by 88%. During the grant period from 2012 to 2018, thirty-two (32) DREAM STEM participants completed STEM degrees with 38% in Physics, 25% in Biology, 19% in Mathematics and 13% in Chemistry. The demographics of the DREAM STEM graduates were: 72% African American, 4% White, 6% Hispanic, 3% Asian and 6% two or more races; and 53% were male and 47% were female. DREAM STEM graduates went on to pursue STEM masters and PhD degrees, to become commissioned military officers deployed on technical assignments and to gain employment in high-tech industry jobs.



**NC Central**  
UNIVERSITY

**Caesar R. Jackson**  
**Professor of Physics**  
North Carolina Central University (NCCU)  
Tel: +1 919 530 5583  
[crjackson@nccu.edu](mailto:crjackson@nccu.edu)  
[www.nccu.edu/academics/sc/artsand-sciences/mathandphysics/dreamstem.cfm](http://www.nccu.edu/academics/sc/artsand-sciences/mathandphysics/dreamstem.cfm)

# INDEX

- Agile Business Consortium..... 414-415  
Alpha-Cat.org ..... 88-90  
Ashridge Executive Education ..... 466-467  
Associação do Instituto Superior Técnico para a  
Investigação e o Desenvolvimento ..... 208-209
- Birmingham Law School..... 380-381
- Cardiff Business School ..... 456-457  
CBDepot s.r.o,..... 84-85  
CeNTI – Centre for Nanotechnology and Smart Materials. . 212  
Climate Service Center ..... 282-283
- Department of Biotechnology and Food Science . . . 306-307  
Department of Cardiovascular and Toracic Science . 150-151  
Department of Chemistry & Biochemistry,  
University of Notre Dame. .... 224-225  
Department of Chemistry, Kansas State University. . 228-229  
Department of Chemistry,  
Virginia Commonwealth University. .... 226-227  
Department of Earth and Atmospheric Sciences . . . 292-293  
Department of Geography - University of Cambridge. . 262-263  
Department of Linguistics,  
Eberhard Karls University Tübingen ..... 424-425  
Department of Mathematics & Physics ..... 480-481  
Department of Obstetrics and Gynaecology ..... 244-245  
Department of Ophthalmology-Visual &  
Anatomical Sciences ..... 132-133  
Department of Ophthalmology,  
Boston University School of Medicine ..... 254-255  
Department of Orthopaedics. .... 168-173  
Department of Physics, Clark Atlanta University . . . 190-191  
Department of Power Mechanical Engineering . . . 136-137  
Department of Statistics - University of Oxford. .... 34-35  
Diabolo (me:my) Limited ..... 470-471  
Division of Musculoskeletal &  
Dermatological Sciences..... 42-43  
Doorda LTD. .... 420-421  
DTU Nanolab ..... 232-233  
DVGW Research Centre at Engler-Bunte-Institute of  
Karlsruhe Institute of Technology (KIT). .... 342-343  
DZNE ..... 162-164
- ECR Retail Systems ..... 366-367  
EMBRC-ERIC  
(European Marine Biological Resource Centre). .... 302-303  
Endocrine Disruptors Project –  
Istituto Superiore di Sanita ..... 240-241  
EP3 Foundation ..... 434-435  
EthnoPharm Group ..... 102-103  
Euroacademy ..... 316  
European Green Cities (ECG) ..... 354-355  
European Industrial Hemp Association (EIHA). .... 94-96
- Faculty of Brain Science, University College London . . 38-39  
Faculty of Geosciences ..... 268-269  
Faculty of Mathematics and Statistics,  
University of St. Gallen ..... 462-463  
FibreShip Project ..... 372-373  
Fika Community Ltd. .... 60-61  
Florida State University Coastal and Marine Lab . . . 312-313  
Fotheringham Associates ..... 408-409  
Fraunhofer Institute for Production Technology IPT. . . 36-37  
Fujitsu PFU (EMEA) Limited. .... 438-439  
Fundacion CANNA ..... 86-87
- GeoCosmo Science and Research Centre ..... 286-287  
Global Aqua Survey Ltd. .... 358-359  
GOJO Industries-Europe Ltd. .... 146-147  
Gowling WLG ..... 404-405  
Greenlight Medicines. .... 74-75  
Greenstat AS. .... 344-345
- HEDPAY Ltd ..... 452-453  
HeLEX - Centre for Health,  
Law and Emerging Technologies ..... 216-217  
Hitachi Consulting ..... 124-125
- InDependent Diabetes Trust ..... 128-129  
INRA. .... 328-329  
Institute for Molecular Medicine Finland ..... 50-51  
Institute of Informatics and Telematics (IIT-CNR) . . . 426-427  
Institute of Nanotechnology,  
Karlsruhe Institute of Technology (KIT). .... 200-201



INTERSPREAD . . . . .	430-431	Rothamsted Research . . . . .	332-333
InventoryClub Ltd . . . . .	442-443	Rutgers University, Graduate School of Education . .	478-479
Jockey Club Centre for Positive Ageing . . . . .	110-111	Savage Cabbage Ltd. . . . .	80-81
Karlsruhe Institute of Technology (KIT). . . . .	198-199, OBC	School of Biosciences, University of Kent. . . . .	246-247
Klinik Healthcare Solutions OY. . . . .	30-31	School of Computing, Electronics and Mathematics – University of Plymouth . . . . .	432-433
LAQV-REQUIMTE/University of Porto . . . . .	210-211	School of Integrative Plant Science . . . . .	320-321
Leiden Institute of Chemistry (LIC) . . . . .	220-221	School of Medicine, University of Dundee . . . . .	274-275
Lewis Silkin LLP . . . . .	388-389	Southern African Centre for Infectious Disease Surveillance (SACIDS) Secretariat . . . . .	140-142
Marburg Centre for Institutional Economics (MACIE) . .	458-459	Storz & Bickel GMBH & CO.KG . . . . .	104-105
MileHigh Labs . . . . .	98-99	Swansea University Medical School . . . . .	22-25
Muroran Institute of Technology . . . . .	362-363	Swedish University of Agricultural Sciences . . . . .	324-325
Nilupul Foundation – Nilupul Centre. . . . .	58-59	Swindon Wiltshire LEP. . . . .	266-267
Northwestern University . . . . .	176-177	Synthesis & Solid State Pharmaceutical Centre (SSPC) . .	194-195
OGEL IT Ltd . . . . .	402-403	Technical University of Denmark. . . . .	348-349
Oh My Mood UK Ltd . . . . .	68-70	The Academy of Medical Cannabis Ltd. . . . .	78-79
Oxford Cannabinoid Technologies LTD. . . . .	76-77	The Bartlett School of Environment Energy & Resources (BSEER). . . . .	278-279
Pfalzkllinikum – Service Provider for Mental Health . .	66-67	The City of Varberg. . . . .	IFC, 260-261
PillTime Ltd . . . . .	120-121	The Kinsey Institute . . . . .	248-249
Placecube Limited . . . . .	406-407	The Sargasso Sea Commission . . . . .	310-311
PLACEmaking . . . . .	396-397, 410-411	twice2much Ltd . . . . .	390-391
Pneumology & Pulmonary Cell Research. . . . .	157-159	UC Davis Department of Molecular Biosciences. . . .	238-239
Polar Research & Expedition Consultancy . . . . .	296-299	UCL . . . . .	28-29
Prashant Dogra, Maria J. Pelaez, Zhihui Wang, Vittorio Cristini . . . . .	114-115	University Hospital Düsseldorf . . . . .	180-181
Professor Colin J Suckling-University of Strathclyde . .	234-235	University Medical Centre. . . . .	152-154
Profil Institut fur Stoffwechselforschung GmbH. . . .	118-119	University of Michigan's Ross School of Business. . .	186-187
Proxima . . . . .	392-393	University of São Paulo, Brazil Institute of Energy and Environment . . . . .	336-338
Relevance Project – Red Blood Cell Research Group . .	54-55	Urban Institute, University of Sheffield. . . . .	374-375
Rivetx Corp . . . . .	446-447	VISIONIST Ltd . . . . .	400-401
		We are BPR Ltd T/A We are Lean & Agile . . . . .	416-417
		Wellbeing Dynamics. . . . .	16-17

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### CONTACT:

Dr. Carlos Ziebert

Head of the Calorimeter Center, KIT, IAM-AWP

+49 721 608 22919, [carlos.ziebert@kit.edu](mailto:carlos.ziebert@kit.edu)

<http://www.iam.kit.edu/awp/english/177.php>

<https://www.openaccessgovernment.org/calorimeter-batteries/53640/>